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ABSTRACT

Under examination at this hearing was the best mechanism for a system of compensation for vaccine injuries. Also considered was the applicability of environmental legislation to vaccines, and whether approval by the Federal Government means that a vaccine is, in effect, as safe as it could be. Statements were presented by representatives of the American Academy of Pediatrics and the American Medical Association and also by experts from the fields of law and medicine. (JD)

S. HRG. 99-222, PT. 2

NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT OF 1985

HEARING

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

NINETY-NINTH CONGRESS

FIRST SESSION

ON

S. 827

TO AMEND THE PUBLIC HEALTH SERVICE ACT TO PROVIDE FOR THE COMPENSATION OF CHILDREN AND OTHERS WHO HAVE SUSTAINED VACCINE-RELATED INJURIES, AND FOR OTHER PURPOSES

DECEMBER 9, 1985

PART 2

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CONTENTS

STATEMENTS

MONDAY, DECEMBER 9, 1985

ADDITIONAL MATERIAL

NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT OF 1985

MONDAY, DECEMBER 9, 1985

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The committee convened, pursuant to notice, at 10:07 a.m., in room SD-430, Dirksen Senate Office Building, Senator Robert T. Stafford presiding.

Present: Senators Stafford and Thurmond.

OPENING STATEMENT BY SENATOR STAFFORD

Senator STAFFORD. The Committee on Labor and Human Resources will please come to order.

Good morning. Thank you for joining this morning and welcome from the Committee on Labor and Human Resources.

The purpose of this hearing is to explore one specific issue which has arisen during the course of this committee's review of S. 827, a bill to compensate the victims of vaccines.

Although the issue has arisen in the context of compensation for vaccine-related injuries, this is by no means the first or only place we have encountered it. It arises in virtually every discussion of victim compensation and liability, whether the particular harm was caused by vaccines, asbestos, radiation, or poisonous chemicals. This issue is whether victims should be required to give up their right to sue as a condition of receiving compensation from the Government.

There are persuasive arguments to make on all sides of this subject. I do not care to recite them at this point, because I expect we will hear them later this morning. I would like, however, to make one observation.

The overriding goal of this and every other system should be to assure that the number of injuries is held to an absolute minimum. This means that the safest possible vaccines should be manufactured in the safest possible manner, packaged with complete and understandable warnings, and finally, administered so that side effects are avoided, and where they nevertheless occur, the injuries are minimized.

The public deserves this standard of care in every circumstance, but it is especially required in this case. This committee has been told that some of these vaccines are unavoidably unsafe. If that is true, then we as a society are quite literally sacrificing some men, women, and children for the greater good. That human sacrifice

should be as small as we can humanly make it; and when the unavoidable injury nonetheless occurs, the victim should be fully compensated. It is for these two reasons that I question why victims should be forced to give up their right to sue as a precondition to receiving assistance from the Government. We know that the compensation afforded individuals under this bill is, in some cases at least, going to be inadequate. For example, the decision has apparently already been made to exclude the cost of life and health insurance as compensable items.

As time and the legislative process continue to work changes in this proposal, it is inevitable that they will be in the direction of lessening compensation and minimizing recovery. Indeed, this will happen by virtue of inflation, if nothing else.

For the inadequately compensated victim, our society leaves only one recourse; that is, litigation. I am a lawyer myself, but I do not like lawsuits. They are expensive, painful and time consuming. But until this committee and the Congress are willing to make a commitment to provide complete compensation and not 1 penny less, we leave victims only one alternative, however unpleasant it may be.

I would add that a fully compensated victim has no reason to sue, nor does the lawyer have any profit to make from taking his case or her case, except of course for punitive damages. There have been suggestions that punitive damage recoveries be limited. I hope some of this morning's witnesses will comment on that. I would be especially interested in knowing whether, in those States where such damages cannot be recovered, the litigation rates are significantly less. I would also be interested in knowing whether we know enough about punitive damages and their effects on the judicial system to adopt as a matter of national policy a prohibition or a limit on their recovery. Of course, punitive damages are awarded only when there has been a fault of some sort. So a countervailing consideration is whether punitive damages influence behavior in some positive way. I should also appreciate hearing comments on this question.

Finally, I would appreciate any comments which the witnesses might have on whether compliance with health and safety regulations or adherence to state of the art should be an absolute defense to liability.

Allow me to say that having served on the Committee on Environment and Public Works for 15 years, I have some acquaintance with this issue. Time and again, as we have written pollution control laws and as they have been implemented, industries have sought, very often with considerable success, to have the requirements weakened and even suspended altogether.

Earlier this year, when the Congress was considering the Superfund legislation, we found some of those same industries asserting that because they had complied with these weakened regulatory requirements, they should be free from liability. That struck some members as a neurotic request.

My understanding is that a comparable suggestion [illegible]ng made here. If extended to other fields, I assume this ap[illegible]h would eliminate liability for injuries caused by DES, the D[illegible]on shield, Thalidomide, and perhaps even asbestos. In the environmental con-

text, it would mean that the Hooker Chemical would have no legal responsibility to clean up Love Canal; Valsacol, for the Valley of Drugs; Allied Chemical, for contamination of the James River, and so on.

While I have dealt with this issue in the context of environmental legislation, I would appreciate any comments witnesses might have as to its applicability to vaccines and whether approval by the Federal Government means that a vaccine is, in effect, as safe as it could be.

So as to leave time for those comments, I will stop here and ask our witnesses to begin to help us. But before we reach the witnesses, I am going to place a statement by the chairman of the full committee, Senator Orrin Hatch, in the record; some questions that he has for witnesses that will be submitted to them for their responses and also a statement on the part of the American Medical Association that will be made a part of the record at the conclusion of the hearing. And further, I will insert a statement by Senator Grassley in the record, sequentially after my own and Senator Hatch.

[The statements of Senators Hatch and Grassley follow:]

OPENING STATEMENT BY SENATOR HATCH

The CHAIRMAN. Today, the Labor and Human Resources Committee again considers the subject of childhood immunization. We have held a number of hearings on this topic, and have discussed its many ramifications at length. The importance of this subject and our responsibilities as legislators require that such extensive deliberating is necessary. In fact, I am heartened that the members of our committee, in the pursuit to do what is right, are taking the prudent course and not rushing to judgment in the face of the great urgency created by the problems in question. Today's hearing is designed to closely examine the issue that is perhaps the most difficult to resolve—the best mechanism for a system of compensation. This is a matter in which Senator Stafford has a great deal of expertise, and it is admirable that he, and other members of the committee, recognize the need to isolate this technical question from the many other related issues. I agree with Senator Stafford's resolve not to report a measure which either sets unwise precedents or becomes unreportable legislation.

Furthermore, compensation is not only a matter of justice, equity, and compassion; it is frankly a matter of money. As we all know, the country is facing, and we are trying to deal with, an enormous Federal deficit. We cannot consider too carefully or deliberate too long about setting up a system, no matter how worthy its goals or how positive its outcome, that will further complicate a problem that many already view as insolvable. In addition, the States and the Federal Government are already struggling with tremendous increases in cost for essential immunization programs. In trying to improve those programs, and make them work better, we must be careful not to create a system which will be so costly as to literally price vaccines out of the market.

Finally, when talking about compensating injury victims, I think we confront some important and complicated questions about the

current tort system. This hearing presents an opportunity to grapple with some of these questions. At a minimum, I hope that the committee does not assume that any change in the tort system will necessarily reduce its effectiveness or result in inequitable treatment of plantiffs. As an attorney myself, I clearly recognize the need for tort action. I also believe that administrative compensation may be, under certain circumstances specified an adjunct or substitute for lawsuits, and may provide a more favorable outcome for some claimants. I am clearly on record, with my own medical malpractice legislation, as favoring tort reform. In the area of vaccine injury specifically, I think it is important to look at combinations of compensation and tort reform, changes that would benefit injured children while not sacrificing the important goal of adequate and complete immunization of all of the children in our country against debilitating, and deadly diseases. A member of the press corps recently commented on seeming endless nature of nuclear arms control talks by saying: "It is better to discuss an issue without resolving it than to resolve the issue without discussing it." I believe that childhood immunization is among the most significant public health issues. Its problems must be dealt with thoughtfully and carefully. They must be resolved in the best interest of the entire immunization program and the best interests of all of the Nation's children. This means we must have the best and safest possible vaccines; we must provide adequate and clear information about immunization and vaccines; and we must deal appropriately with compensation for vaccine-related injuries. In the end it is our children whose health and lives will benefit from the thoughtful deliberation of this committee.

[The prepared statement of Senator Grassley follows:]

STATEMENT BY SENATOR GRASSLEY REGARDING VACCINE INJURIES AND COMPENSATION ON DECEMBER 9, 1985.

MR. CHAIRMAN, I THANK YOU FOR ORGANIZING THIS HEARING ON AN APPROPRIATE COMPENSATION SYSTEM FOR VACCINE INJURIES AND ITS RELATION TO REDRESS THROUGH THE TORT CLAIMS SYSTEM. I APPRECIATE THE OPPORTUNITY TO HEAR ADDITIONAL TESTIMONY ON THIS IMPORTANT ASPECT OF THE VACCINE INJURY PROBLEM.

I HAVE MET SOME OF THESE CHILDREN AND THEIR PARENTS AT LISTENING POSTS I HOLD IN IOWA EACH WEEKEND. WHAT HAS HAPPENED TO THESE CHILDREN IS HEART RENDING. NO GREATER DISASTER COULD HAVE BEFALLEN THEM AND THEIR FAMILIES. THEREFORE, I TRUST WE ARE NOT TOO FAR FROM BEING ABLE TO REPORT OUT A BILL WHICH WILL BE ACCEPTABLE TO A MAJORITY OF THE COMMITTEE, AND WHICH WILL PROVIDE SOME RELIEF TO THOSE CHILDREN WHO HAVE BEEN INJURED AND TO THEIR PARENTS, WHILE AT THE SAME TIME NOT THREATENING THE VIABILITY OF OUR IMMUNIZATION PROGRAM FOR THIS DISEASE.

I LOOK TO OUR WITNESSES TODAY TO PROVIDE INSIGHT INTO SOME OF THE IMPORTANT ISSUES RAISED BY OUR EFFORTS TO COME TO GRIPS WITH THIS PROBLEM. FOR EXAMPLE, I WOULD LIKE TO KNOW WHETHER OUR WITNESSES SEE VACCINE INJURIES AS UNIQUE IN THE PRODUCT LIABILITY AREA, THUS JUSTIFYING SPECIAL COMPENSATION ARRANGEMENTS. I WOULD LIKE TO KNOW WHAT EFFECT ESTABLISHMENT OF DIFFERENT COMPENSATION ARRANGEMENTS WOULD BE LIKELY TO HAVE

ON THE RESORT BY INJURED PARTIES TO THE TORT CLAIMS SYSTEM. RELATED TO THIS IS THE QUESTION OF WHAT EFFECT OUR WITNESSES THINK VARIOUS COMPENSATION ARRANGEMENTS WILL HAVE ON THE ABILITY OF THE VACCINE PRODUCERS TO CONTINUE PRODUCING AND MARKETING THE VACCINE.

NO DOUBT MANY OTHER QUESTIONS WILL BE RAISED DURING OUR HEARING, AND I LOOK FORWARD TO THE DISCUSSION THEY GENERATE. THAT IS ALL I HAVE TO SAY FOR NOW, MR. CHAIRMAN.

Senator STAFFORD. Having gotten through that, ladies and gentlemen, we will ask the first panel to come to the witness table.

The panel will consist of Dr. Richard M. Narkewicz, who is a pediatrician from Burlington, VT, a board member of the American Academy of Pediatricians, and a gentleman I am especially happy to welcome here, since I share with him citizenship in the State of Vermont.

Dr. Narkewicz, if you will come forward, please.

Also, Dr. Martin Smith, who is president of the American Academy of Pediatrics.

May I, on behalf of the committee, welcome you both to the meeting this morning. If you have some preferred sequence of presentation, we will live by it; usually, a president gets precedence around here.

Dr. Smith, we would be pleased to hear from you.

STATEMENT OF DR. MARTIN SMITH, PRESIDENT, AMERICAN ACADEMY OF PEDIATRICS, AND DR. RICHARD M. NARKEWICZ, PEDIATRICIAN, BURLINGTON, VT, AND MEMBER, AMERICAN ACADEMY OF PEDIATRICS

Dr. SMITH. Thank you, Mr. Chairman and members of the committee.

I am Dr. Martin H. Smith, a pediatrician in private practice from Gainesville, GA, and president of the American Academy of Pediatrics, and with me is Dr. Richard Narkewicz, a pediatrician in private practice from Burlington, VT, and a member of the Academy of Pediatrics Executive Board.

We appreciate the opportunity to testify once again on the critical need for Federal legislation designed to establish a no-fault system to compensate children and their families for medical and other expenses arising from adverse reactions to childhood vaccines.

In our view, legislation is necessary for at least four reasons: First, to provide just and certain compensation for mandated childhood vaccines; second, to stimulate development and production of new and less-reactive vaccines in the near future; third, to ensure that adequate information is made available to physicians and parents regarding these vaccines; and finally, to ensure that existing childhood vaccines are not abruptly withdrawn from the market.

We understand that today's hearings will focus on two related proposals which may be offered as amendments to S. 827.

The first proposal, drafted by Senator Stafford, provides that all claims for injuries resulting from childhood vaccines must first be filed under the National Vaccine Injury Compensation Program, and that notwithstanding any claim received under the program, action can subsequently be filed in a State or Federal court. Compensation may be made only on the condition that it would be repaid from the proceeds of any sums awarded in a judgment if they have proceeded to the judicial system.

Under the second approach advanced by Senator Dodd, compliance with production and administration of standards established by the Federal Government would afford manufacturers and providers protection in judicial proceedings.

Mr. Chairman, the academy endorses the objectives of both such proposals and hopes to work with the Senators on this committee and their staff to see that those objectives are realized in legislation which you report to the Senate floor.

Let me make clear there can be no doubt as to the need for this vital piece of legislation. We are not dealing simply with a compensation program for damaged children. We are protecting the most basic and valuable public health program we have in existence today. The threat to our vaccine supply in this country is a real one. The loss of vaccine manufacturers coupled with the rapid escalation in vaccine costs could place our children at risk of preventable diseases. We could lose the remainder of our suppliers unless some positive legislative action is taken.

The academy has been an active participant in most of the Senate deliberations, both formal and informal, on this issue. The concept has received strong bipartisan support, and we are now at the point of fine-tuning and crafting a responsible public policy.

[The prepared statement of the American Academy of Pediatrics follows:]

American Academy of Pediatrics

[redacted]

BEFORE THE

[redacted]

UNITED STATES SENATE

ON

[redacted] COMPENSATION

[redacted]

PRESENTED BY

[redacted]

and

Richard H. [redacted], M.D.

[redacted]

Office of Government Liaison
[redacted]
Washington, D.C. [redacted]
[redacted]

Introduction

Mr. Chairman and members of the Committee, I am Martin H. Smith, M.D., a pediatrician in private practice from Gainesville, Georgia, and President of the American Academy of Pediatrics. With me today is Richard M. Narkewicz, M.D., a pediatrician in private practice from Burlington, Vermont, and a member of the Academy's executive board.

We appreciate the opportunity to testify once again on the critical need for federal legislation designed to establish a no-fault system to compensate children and their families for medical and other expenses arising from adverse reactions to childhood vaccines. In our view, legislation is necessary for at least four reasons: to provide just and certain compensation for medical and other expenses for injuries associated with legally mandated childhood vaccines; to stimulate development and production of new and less reactive vaccines in the near future; to insure that adequate information is made available to physicians and parents; and finally, to insure that existing childhood vaccines are not abruptly withdrawn from the market.

We understand that today's hearing will focus on two related proposals which may be offered as amendments to S. 827. The first proposal, drafted by Senator Stafford, provides that all claims for injury resulting from childhood vaccines must first be filed under the National Vaccine Injury Compensation Program and that, notwithstanding any claim

received under the Program, action may subsequently be filed in a state or federal court. Compensation may be made only on the condition that it be repaid from the proceeds of any sums awarded in a judgment or settlement of the judicial claim. Under the second approach, advanced by Senator Dodd, compliance with production and administration standards established by the Federal Government would afford manufacturers and providers protection in judicial proceedings.

Mr. Chairman, the Academy endorses the objectives of both such proposals and hopes to work with Senators on this committee and their staff to see that those objectives are realized in legislation which you report to the Senate floor.

Problems With Childhood Vaccines

We believe it may be helpful to summarize the existing "state of the art" concerning childhood vaccines, the threat to their continued availability, and hopes for the future.

Although childhood vaccination programs undoubtedly have saved the lives of hundreds of thousands of children, the vaccines themselves are not innocuous. While there is some risk associated with all vaccines, the pertussis (whooping cough) vaccine is the most reactive. Data derived from a British study, the National Childhood Encephalopathy Study (1976-1979) indicate that brain damage may occur after vaccination in one of every 310,000 cases.

Many lawsuits have been filed against manufacturers of pertussis vaccine alleging neurologic damage; this reportedly has been a major factor in the decision of several manufacturers to discontinue production. The limited number of manufacturers was a significant contributor to a temporary vaccine shortage this past summer. The Academy is very concerned with the declining number of manufacturers of this vaccine and reports that the small number of still existing manufacturers are considering withdrawing their products from the market because of massive numbers of lawsuits.

Potential for Newer, Improved Vaccines

Recent advances in biotechnology offer new approaches to many previously intractable problems of vaccine production. These technologies, combined with a better understanding of the immunological process, have opened a new era in vaccine development.

An effective, safer vaccine against pertussis is under study in this and in other countries. There is no immediate prospect, however, that such a vaccine will be available in the near term. Although progress is reported in these studies, newer vaccines cannot be put into general use here in America without extensive, time-consuming field trials. Hence supplies of the current vaccine must remain available and in ready supply.

In the meantime, the number of lawsuits against vaccine manufacturers continues to rise. In our view, the existence of these lawsuits, coupled with the relatively low profit margin gained from the sale of vaccines, will deter introduction of a second generation of childhood vaccines unless legislative changes in the tort system are forthcoming.

The Academy's Position on the Stafford and Dodd Proposals

With this background, we offer the following comments on the Stafford and Dodd proposals:

1. The Stafford Proposal

S. 827, which the Academy assisted the Committee in developing, poses a choice for parents: they either can pursue the no-fault approach offered by the Program, or they can pursue a lawsuit, but not both. The Stafford approach requires an injured party to pursue the no-fault approach first, preserving an option to pursue subsequent judicial remedies, with assurances against dual collection. The Academy endorses this approach as an acceptable alternative to the "choice up front" requirements of the bill. The table of compensable events in S. 827 is generous enough to provide just compensation to children injured by a vaccine. Its provisions--coupled with the requirement that the no-fault approach must be pursued prior to consideration of a lawsuit--should be attractive enough to forestall most court.

59-407 O - 86 - 2

actions. Data from experience with the New Mexico medical malpractice law seem to support our assumption. We believe that the Stafford approach holds the promise for certain and just compensation under the no-fault approach, while preserving the tort system for the most egregious cases. For reasons set forth below, we urge that this approach be accompanied by changes in the tort law to provide adequate predictability to manufacturers and to ensure that they are not held liable in the absence of genuine misconduct.

2. The Dodd Proposal

Mr. Chairman, we appreciate the efforts put forth by Senator Dodd to balance two competing and valid arguments: first, that manufacturers of childhood vaccines need protection from costly litigation in order to assure that vaccine production and marketing continue; and second, that the tort system can be a valuable consumer protection tool, ensuring commitment to careful, non-negligent manufacture and distribution of the safest possible products.

We believe that an amendment designed to achieve a balance between these equally valid positions would vastly improve the bill before you today.

As observed by the Institute of Medicine in its report "Vaccine Supply and Innovation" (1985) (p. 148), "vaccine supply and administration are sufficiently different from other injury-causing behaviors to justify separate treatment." These differences include:

- nature of the vaccine industry: manufacturers of vaccines play an integral role in national public health policy by producing necessary vaccines. Yet most manufacturers operate at a low profit margin, due to high research, development and production costs, high cost of skilled employees in a labor-intensive manufacturing process, and the need to maintain a relatively modest price structure to ensure availability of vaccines to state and federal governments at relatively low prices;

- lack of free choice: Most immunization programs are mandatory. Thus, the concept of calculated risk-taking by the doctor or patient is inapplicable except in rare cases;

- decline in vaccine manufacturers: Given the threat of liability and the prospect of producing more lucrative drugs, many manufacturers have stopped producing vaccines; and

- unpredictability of vaccine-related claims under the tort system: Courts have been unable to fashion a predictable standard of liability under the common law tort system. 1/

For these reasons, Mr. Chairman, we support changes in the tort system itself, with respect to childhood vaccines. While we do not support caps on recovery amounts, we recognize that the tort system must result in more predictable outcomes.

Accordingly, we would support an amendment to S. 827 that would establish compliance with federal standards for vaccine testing, manufacturing and labeling as an affirmative defense

1/ See E. Kitch, Vaccines and Product Liability: A Case of Contagious Litigation, Regulation (May/June, 1985).

in a civil lawsuit. Under our proposal, a vaccine manufacturer would not be held liable if its product were listed in the Vaccine Injury Compensation Table and the vaccine were tested, manufactured, distributed, and labeled in accordance with Food and Drug Administration requirements. A similar provision would apply to health care providers who administer such vaccines in accordance with the guidelines of the Advisory Committee on Immunization Practices of the U.S. Public Health Service. We believe that the FDA requirements, which would serve as an affirmative defense, should be developed only after extensive public participation in rule-making proceedings by scientists, physicians, manufacturers and parents. The requirements should not serve as a defense until these rule-making proceedings have been finalized.

Mr. Chairman, we believe that the approach offered by the Stafford and Dodd proposals represents a fair, balanced approach. Generous and certain compensation would be assured under the no-fault program. Access to the tort system is retained. Manufacturers would know in advance that compliance with government standards, adopted only after full public participation, would constitute an affirmative defense in a products liability action. Providers would be assured that compliance with government standards for administration--again,

adopted only after full public participation--would relieve them of medical malpractice claims.

We understand Senator Stafford's concern that this approach might serve as precedent for legislative action concerning other products, such as asbestos and Agent Orange. We have no difficulty whatsoever drawing a distinction between the latter products and valuable childhood vaccines, which are purchased in large part by the Federal Government, whose use is made mandatory by all states, and whose continued existence and improvement are threatened by massive numbers of lawsuits despite almost universal agreement as to their value.

Mr. Chairman, allow me to quote from a California appellate case involving liability for injury caused by the polio vaccine. Although the quote is lengthy, we believe that it is directly pertinent to the issue of different treatment of vaccines under the tort system.

> The prospect that a [vaccine] manufacturer might be subject to [standards generally applicable in products liability litigation] may cause delay in marketing of products while manufacturers conduct various safety tests; <u>in some cases the prospect of such review and concomitant increased likelihood of liability may deter research, manufacturing and marketing altogether</u>. It is apparently assumed that such a result is socially beneficial in the vast majority of products cases: we are often willing to sacrifice speedier marketing of products, or we may be willing to sacrifice availability

altogether, in return for greater accountability of manufacturers through imposition of strict liability. Although this may be an appropriate trade off when we are considering designs of appliances, cars, hand tools, or food, it might not be appropriate with regard to some special products that are extremely beneficial to society and yet pose an inherent and substantial risk that is unavoidable at the time of distribution.

* * *

. . . we can easily conceive of situations in which a manufacturer's cost of insuring against strict liability for injuries resulting from product design would place the cost of research development and eventual marketing of new [products] beyond that which manufacturers, especially smaller manufacturers, are willing to risk . . . .

Furthermore, we believe it likely that the increased cost of product production -- resulting from increased insurance costs -- might place the price of necessary [products] out side the reach of those who most need them, or that the prospect of strict liability might cause manufacturers to remove some products from the market, or decline to develop them.

All of this suggests that this regard to some special products the scale may tip away from enhanced accountability (i.e., strict liability analysis of design defect claims) and in favor of availability. It follows that to facilitate, and not to frustrate availability in those special cases, some special products should be exempted from the normal strict products liability design defect analysis; instead of judging such products in the light of ordinary consumer expectations or present scientific knowledge, they should be

> reviewed according to the state of the art -- i.e., the manufacturer's actual or constructive knowledge -- at the same time of marketing. 2/

Mr. Chairman, we agree with the analysis of the California appellate court, and believe that for the reasons advanced by the court -- as well as many other expert bodies -- vaccines deserve special treatment by the Congress, as well as the courts.

Mr. Chairman, we renew our sincere appreciation for the hours this Committee has spent perfecting S. 827. We renew our pledge to continue working with you in this effort on behalf of all children.

2/ Kearl v. Lederle Laboratories, ___ P.2d ___, 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (Cal. Ct. App. 1985). (Emphasis added and citations omitted). The court held that although in "standard products liability litigation a plaintiff may utilize a strict liability design defect theory, such a strict liability cause of action must be prohibited for public policy reasons if the court determines, after taking evidence, that the product complained of is 'unavoidably dangerous'"; the court stated that in "such special cases, a plaintiff may proceed on a design defect theory only on the basis of negligence." Id.

Dr. NARKEWICZ. With this background, I would like to turn to Senator Stafford's proposal. S. 827, which the academy assisted the committee in developing, poses a choice for parents. They either can pursue the no-fault approach offered by the program, or they can pursue a lawsuit, but not both.

The Stafford approach requires an injured party to pursue the no-fault approach first, preserving an option to pursue subsequent judicial remedies with assurance against dual collection. The academy endorses this approach as an acceptable alternative to the choice upfront requirements of the current bill.

The table of compensable events in S. 827 is generous enough to provide just compensation to children injured by the vaccine. Its provisions, coupled with the requirement that the no-fault approach must be pursued to consideration of a lawsuit, should be attractive enough to forestall most court actions.

Data from experience with the New Mexico medical malpractice laws seem to support our assumption. We believe that the Stafford approach holds the promise for certain and just compensation under the no-fault approach, while preserving the tort system for negligence cases and unresolved compensation conflicts or complications.

For reasons which will be discussed later, we urge that this approach be accompanied by changes in the tort law to provide adequate predictability to producers and providers and to ensure that they are not held liable in the absence of genuine misconduct.

Senator Stafford, no one can match your exemplary track record with respect to your leadership in protecting the citizens of this country from environmental hazards, but we do have the technology I must also add that your special concerns for children have our greatest admiration. We pediatricians also have a track record with respect to protecting the children of this country from environmental hazards. The hazards I am speaking about today are the common childhood diseases that kill and injure our children: measles, mumps, German measles, polio, diphtheria, whooping cough, and lockjaw.

Presently, we do not have the technology to clean up these environmental hazards, but we do have the technology to prevent these diseases. The only way we can protect our children from these diseases is to give the children appropriate protective immunizations.

The tremendous success of this most basic and valuable public program should be apparent to everyone. Unfortunately, a small number of children are injured by adverse reactions in the process of protecting a large number of children from being killed or injured by these preventable diseases.

A series of events happened in the State of Vermont and the rest of the Nation that should highlight the fragility of our Nation's immunization programs. Last year, there was a pullout of all but two DPT manufacturers, and due to technical problems there was a scarcity of DPT vaccine. Many areas ran out of DPT and could not get new supplies. The Academy of Pediatrics and the Center for Disease Control recommended we selectively withhold some DPT shots while the supply was scarce.

In Vermont, due to a few pockets of poorly immunized population, we experienced 25 cases of pertussis, whooping cough. Most of

these were children under the age of 1 year and were very ill; one small child died, and one is still undergoing complications. All of this happened at a time when our State health department budget was forced to increase from $3,300 to $88,000. Yes, $3,300 to $88,000, just to purchase the same amount of childhood vaccines.

The combination of reduced numbers of vaccine producers, reduced and inadequate vaccine supply, the escalating cost of vaccine, and the ever-present diseases in the environment waiting to explode with the opportunity points to the acute crisis we are facing.

This experience also highlights a medical point that needs to be stressed. The causative agents for these preventable childhood illnesses are ever present in the environment, waiting for the opportunity to attack the unprotected individual. Once a person has contracted one of these diseases, the treatment is only systematic and supportive, because modern medicine does not effectively stop the course of these diseases. The only effective medical weapon we have in our black bag now that is effective against these diseases is the use of appropriate immunizations to prevent the individuals from contracting these diseases.

Our bottom line is the same as yours. We do not want any more children injured or killed by these preventable diseases. We do not want any more children inadvertently injured by adverse reactions in the immunization process. Until these ultimate goals are realized, we need a continuing source of vaccine, progress on the production of new and better vaccines, relief from the escalating costs of vaccines, and a system of fair and just no-fault compensation for victims of serious adverse reactions to vaccinations.

We feel the National Childhood Vaccine Injury Compensation Act, S. 827, is a mechanism to allow us to move onward toward our ultimate goals. We feel, Senator Stafford, that your amendment which preserves the option for the tort system will be a valuable stimulus for consumer protection and careful, nonnegligent manufacture and distribution of the safest possible immunizing products. We feel this amendment strengthens the bill and are pleased that all of you and your staff are dedicated to help us achieve our ultimate goals.

Dr. SMITH. Let me turn to the proposal put forth by Senator Dodd to balance two competing and valid arguments. First, that manufacturers of childhood vaccines need protection from costly litigation in order to assure that vaccine production and marketing continue; and second, that the tort system can be a valuable consumer protection tool in ensuring commitment to careful, nonnegligent manufacture and distribution of the safest possible products.

We believe that an amendment designed to achieve a balance between these equally valid positions would vastly improve the bill before us today.

As observed by the Institute of Medicine in its report, "Vaccine Supply and Innovation in 1985," page 148, vaccine supply and administration are sufficiently different from other injury-causing behaviors to justify separate treatment. These differences include the nature of the vaccine industry. First, it is an industry with a limited market, with a relatively marginal profit as compared to other products. Second, the lack of a free choice. This product is mandat-

ed in most States and in most instances of the vaccines. Third, there is a decline in vaccine manufacturers. As we know, most of the vaccines produced now are by mono producers so that we have a single, uncompetitive supplier of our vaccines. Fourth, there is an unpredictability of vaccine-related claims under the present tort system.

Accordingly, we would support an amendment to S. 827 that would establish compliance with Federal standards for vaccine testing, manufacturing, and labeling as an affirmative defense in a civil lawsuit. Under our proposal, a vaccine manufacturer would not be held liable if its products were listed in the vaccine injury compensation table and the vaccine were tested, manufactured, distributed and labeled in accordance with Food and Drug Administration requirements.

A similar provision would apply to health care providers who administer such vaccines in accordance with the guidelines of the Advisory Committee of the Immunization Practices of the U.S. Public Health Service. We believe that the FDA requirements which would serve as an affirmative defense should be developed only after extensive public participation in rulemaking proceedings by scientists, physicians, manufacturers, and parents. The requirements should not serve as a defense until these rulemaking procedures have been finalized.

Mr. Chairman, we believe that the approach offered by the Stafford and Dodd proposals represent a fair, balanced approach. Generous and certain compensation would be assured under the no-fault program. Access to the tort system is retained. Manufacturers would know in advance their compliance with Government standards, adopted only after the full public participation would constitute an affirmative defense in a product liability action. Providers would be assured that compliance with Government standards for administration would relieve them of medical malpractice claims.

We can certainly understand your concern that this approach might serve as precedent for legislative action concerning other products such as asbestos and agent orange. We have no difficulty whatever drawing a distinction between the latter products and the various childhood vaccines, which are purchased in large part by the Federal Government, whose use is made mandatory by all States, and whose continued existence and improvement are threatened by massive numbers of lawsuits, despite almost universal agreement as to their value.

A California appellate court, as well as other expert bodies, have upheld this analysis.

Mr. Chairman, we renew our sincere appreciation for the hours this committee has spent perfecting S. 827. We renew our pledge to continue working with you in this effort on behalf of all children.

Thank you.

Senator STAFFORD. Thank you very much, doctors, for your helpful testimony. I do have a few questions, and for members who are not able to be here, I am going to reserve the right to submit questions in writing, if that is agreeable, for your reply at your convenience.

Dr. SMITH. Surely.

Senator STAFFORD. To both of you, I would ask this series of questions, and I will try to make the preliminary statement and then ask the questions one at a time.

Doctors, could you describe for the committee exactly what procedure you follow in administering the DPT and oral polio vaccines? Specifically, I would appreciate knowing the following. First, as to polio vaccine, do you as a matter of routine ask whether the child lives with or will be visiting a person who has not been immunized for polio? If you do ask this question, is this because of material contained in the package insert?

Now, either or both of you may answer these as you wish.

Dr. SHERR. Let me ask Dr. Narkewicz to answer this and tell you exactly how he does it in his office in Vermont.

Senator STAFFORD. All right.

Dr. NARKEWICZ. Senator Stafford, in Vermont we are very, very fortunate because we have close cooperation with our State Health Department, which supplies us with the vaccine that we use on the children of Vermont. In my office in particular—and I can speak for probably the majority of the pediatricians in the State—the answer is affirmative. What we do in essence is we have our nurses talk and ask them these specific questions.

We do have a form that probably is used throughout the country, and we have the parents read this form. And actually, the questions that you ask are posed in this form. We have them read it and sign it, and then when I see the patients, I talk with them about these two issues and ask them if they have any questions, advise them of the risks, but I always finish up by saying, "I understand that there is a risk; there is a risk to a lot of things. But in my medical opinion, I feel that the risk of the disease far outweighs the risk of the immunization."

Senator STAFFORD. Possibly, in that series of questions you have the patients or their parents read is answered in the remaining questions, but let me ask them.

In administering the DPT vaccine, do you ask whether there is a history of nervous disorders or seizures in the family?

Dr. NARKEWICZ. Yes; we do. As a matter of fact, we have the five or six contraindications to DPT posted now in all of the waiting rooms and also in all of the examining rooms, so that patients have the opportunity to read these first.

Senator STAFFORD. Do you telephone the parents afterward to see if there has been any reaction to the vaccination?

Dr. NARKEWICZ. I am sorry. We do not do that. That probably is a little unpractical. But you can bet your life that they telephone us if they do have one.

Dr. SHERR. They are asked to, I think, in most offices; we tell them to please call.

Senator STAFFORD. Do you ever test a child for sensitivity to the vaccine before administering it?

Dr. SHERR. There, I am afraid, is no real method of testing. If there were a dependable method of testing, we would certainly use it, but we have no method of testing for this knowledge in advance.

Senator STAFFORD. Finally, do you ever allow a nurse or other nonphysician medical personnel to administer the vaccine?

Dr. NARKEWICZ. In our office, yes, we do; our nurses give our immunizations—but only under the direction of the physician.

Senator STAFFORD. All right. Now I have got a question of considerable length. In your testimony, especially Dr. Smith, but to both of you, you expressed support for the proposition that compliance with Federal production standards should be an absolute defense to liability. Most attention in this committee has focused on the DPT vaccine and the injuries caused by it. But the oral polio vaccine has also been proven to cause injuries. As a matter of fact, this committee has been provided with an internal corporate memorandum in which a company scientist described to his superiors the manner in which the oral vaccine could cause injuries and recommended that the package insert be changed. In the alternative, he suggested that Federal law should be changed so the company would be shielded from liability.

A few years after the date of this memorandum, a farmer was stricken with polio in exactly the manner described by the scientist's memorandum. I take it that your position is that the farmer should not have been able to recover, even though the company knew that his injury could occur and believed that its package insert was inadequate to warn doctors and patients of this possibility.

Is that your position?

Dr. SMITH. I would have to say that I think that what you are describing outlines the present-day situations, or the present-day package inserts, and the situation that pertains today. In our testimony, we stated that we would want this to be subject to a full review and regulation—setting by due process when this law goes into effect, so that we hope that any discrepancies in package inserts and in the information that is available and should be available have been eliminated.

We have never advocated any shielding of any vaccine producer or of any doctor if there has been any fault involved.

Senator STAFFORD. All right. Let me pursue this a bit further. It would seem to this Senator that implicit in your support for the state-of-art defense is the principle that whatever the Federal Government requires is the most a doctor or manufacturer should be required to do. In other words, if Federal regulations authorize the marketing of a drug of 98 percent purity, there is no liability even if it could be manufactured to 99.9 percent purity for slightly more money. Is that correct?

Dr. SMITH. I would expect that if available methods that can be applied to any vaccine that would improve it further, that the ability to change the regulations affecting the vaccine production would force the improvement in the vaccine.

Senator STAFFORD. It also seems implicit that Federal standards do and should constitute the state of the art; in other words, whatever the Government requires is the best that a person could or should do. Is that correct?

Dr. SMITH. I am sorry. I did not understand the question.

Senator STAFFORD. All right—if either or both of you would prefer to answer these questions in writing, we would be glad to have it done that way.

But the question is, it also seems implicit that Federal standards do and should constitute the state of the art; in other words, whatever the Government requires is the best that a person could or should do. Is that correct?

Dr. SMITH. That should be correct. We should expect that that would happen.

Senator STAFFORD. Also implicit in your support for such an amendment is a belief that the law should be the same in each and every one of the 50 States—that is, no State could choose to require a safer vaccine or safer procedures. Is that correct?

Dr. SMITH. If the regulations involved for the Federal Government are good enough, I would expect that there should not be a necessity for a State to try to improve upon it.

Senator STAFFORD. I think that is a pretty good answer.

As you know, under current Federal law, gasoline containing lead can be sold throughout the United States, even though the lead is estimated to cost some 50,000 excess deaths from stroke and heart attack in males over age 40. It also is believed to cause diminished intelligence in children. Assume just for the sake of argument that a man your age had a stroke and could prove that lead in gasoline was a contributing factor. Do you believe the chemical company should be absolutely immune from liability on the grounds that the Federal Government explicitly authorized leaded gasoline?

I concede that is a purely hypothetical question.

Dr. SMITH. I would have trouble making that transition.

Dr. NARKEWICZ. I would not because clearly, in my mind, if we are applying this hearing to vaccines, and we are trying to apply it to vaccines, the vaccines are mandated, and they are given for a purpose which is different—you do not have to put gas in your car—you are not mandated to do that. So I would draw a distinction in my own mind between that and the vaccine manufacturing.

Dr. SMITH. I would agree.

Senator STAFFORD. All right. I think that is a good answer.

I think I am going to thank you both very much and remind you that some of my colleagues might have questions in writing which they would appreciate, and I would, your responding to at your early convenience, if that happens.

Dr. SMITH. Surely.

Senator STAFFORD. And for the committee and myself, our deep appreciation for the trouble you have gone to to be here and help us with this problem this morning.

Dr. SMITH. Thank you.

[Responses of Dr. Smith to questions submitted by Senator Hatch follows:]

DR. SMITH'S RESPONSES TO QUESTIONS FROM SENATOR HATCH

1. Question. What is the Academy's position about the need to incorporate reasonable limitations on tort liability into any vaccine compensation legislation?

Answer. Given the fact that vaccine-related injuries do occur that are truly no one's fault—not the manufacturer or the administrator of the vaccines—reasonable limitations on tort liability should apply. However, in the case of negligence or wrongful conduct on the part of either party, we would be less generous in our thinking.

2. Question. Would the Academy support a limit on the amount of non-economic damages that could be awarded in a vaccine tort suit, similar to the limits included in some state medical malpractice laws?

Answer. Yes, we would. S. 827 currently does contain a cap on pain and suffering and does not provide any punitive damages. We support that and would consider other options in this regard.

Dr. NARKEWICZ. Thank you, Senator. The academy appreciates it.

Senator STAFFORD. And let me wish you both a very merry Christmas and happy New Year, and Dr. Narkewicz, maybe I will see you sometime in the course of that week.

Dr. NARKEWICZ. I hope so.

Senator STAFFORD. But not professionally.

The second panel will consist of Mr. Dwight A. Corrin, Esq., of Corrin & Krysl; Dr. Marshall S. Shapo, professor, Northwestern University School of Law; and Mr. Anthony Colantoni, Esq., McDowell & Colantoni.

Gentlemen, once again, the Chair would be delighted to have your proceed in accordance with your own wishes as to speaking order; if you have none, we would go in the order in which we called your names, which would mean Mr. Corrin, followed by Mr. Shapo, followed by Mr. Colantoni.

Is that agreeable?

Mr. CORRIN. Fine.

Senator STAFFORD. All right, then, Mr. Corrin, we will hear from you.

STATEMENT OF DWIGHT A. CORRIN, ESQ., CORRIN AND KRYSL; DR. MARSHALL S. SHAPO, PROFESSOR, NORTHWESTERN UNIVERSITY SCHOOL OF LAW, AND ANTHONY COLANTONI, ESQ., McDOWELL & COLANTONI

Mr. CORRIN. Mr. Chairman, I would like to thank you for the opportunity to be here today. It is not very often that a person gets to sit and address this august body or any portion of it, and I appreciate it very much.

I believe that I can probably contribute the most by discussing first of all my own contact with these problems.

I believe that one of the questions that you read to the last witnesses alluded to my client, Mr. Emil Johnson, who used to be a farmer in Lawrence, KS, farmed about 500 acres of ground, and in the course of attempting to be socially responsible and fulfill his duties in that respect, he took his daughter to a pediatrician to be immunized against polio, and as a result of his daughter being given the live vaccine, he contacted polio and now his breathing capacity is completely debilitated; he has paralysis of the muscles in his chest.

I think most people in this country would be pretty surprised to find out a person could get polio from taking the vaccine, but would be even more amazed to find out a person could be given polio because someone they came into contact with socially had been given a vaccine.

Emil Johnson has permanent paralysis of his upper trunk, and his breathing ability is seriously impaired. Most of us breathe without even thinking about it, and Emil Johnson now has to fight for every breath. Six times a day, every 4 hours, when he is in the best

of health, he has to go through a procedure where, through his tracheotomy, he has to spray a mist and medication into his lungs to break up the fluids that collect there so that he can attempt to get them out of his lungs, because he does not have the muscular ability to do it naturally like the rest of us do.

He is unable to cough because of the injuries to his muscles. So it is a real struggle for him just to be able to keep oxygen going through his body.

Senator STAFFORD. Has he lost the control of his limbs? Is he able to walk?

Mr. CORRIN. He is able to walk, although he is not able to walk very far because of the fact that——

Senator STAFFORD. Lack of oxygen.

Mr. CORRIN [continuing]. He cannot keep up with the breathing. So he is constantly at risk to respiratory problems, and he cannot work anymore. He tries, because he is not used to being sedentary, once in a while to do things his doctors tell him not to do. But he pays for that. I know at one time, he went out and tried to do some plowing—this was several years ago—and as a result of that he went from having to take steroids once every 2 days back to having to take them daily, and he has never been able to get his medication level on the steroids back down to where it was before he did that work.

I understand that it has been suggested in these Halls that no Kansas farmer is worth the amount of money that he was awarded and that there is really nothing wrong with him. I think that that is—well, I do not know—I think a Kansas farmer is worth just as much as a New England lawyer or a Kansas lawyer or any of the rest of us. Mr. Johnson was awarded $2 million in actual damages and also received an award of $8 million in punitive damages. That award is on appeal at this time before the Kansas Supreme Court.

Senator STAFFORD. Oh, the Kansas Supreme Court; is that where it is?

Mr. CORRIN. Yes. Now, I believe attached to my statement is the memorandum that was sent in 1968, which I think the question you read to the last witnesses was alluding to, in which the recommendation was made to Lederle Laboratories that they provide more information to the doctors that administer the vaccine, and they recommend that the doctors pass this information on to the patient. Now, that memorandum was sent more than 7 years before Emil Johnson got polio, and the recipient of that memorandum, according to his own testimony, his response to the memorandum was to wad it up and throw it in the wastebasket.

What one would expect would be, I think, that at least it would be discussed with his colleagues and maybe circulate the memo among the other doctors in the company and see whether the doctor who sent the memo had a good idea, or what they should do about it. And instead, he just decided on his own, "Well, the heck with that. We are selling the vaccine," and threw it in the trash.

I believe that is the core of the basis for the award of punitive damages—that, and there is considerable other evidence in the record which also supports the fact that American Cyanamid knew, or should have known, that they needed to do more. Their position

is that the Government did not make them do more, so that is all they needed to do.

I think the real danger of letting these Government standards be a complete defense, is that even if at the time those standards are promulgated, they are the best standards that you can get, they do not take into account the changing knowledge in the drug industry and the medical profession. It is not going to be more than a few weeks or a few months before the industry knows more than the Government knew when the standards were promulgated. We all know inertia is one of the things that happens in Government, as well as everywhere else, or maybe even a little more, and so those standards, while they might be adequate for a while, are not going to stay adequate for as long as they are going to stay the standards.

Now, the other thing that you are talking about is caps. I think that caps on awards, the only people that are injured by caps are the people that have the worst injuries. Somebody that is not so seriously harmed and who would be entitled to an award of the amount of the cap or less, the cap is not going to hurt them. The only people that are going to be affected by the cap are the people that are hurt a lot more than that.

And as far as the cap on the punitive damages, a cap on punitive damages would completely—they would have just as much of a negative effect on causing punitive damages to achieve their stated goal as not having any punitive damages at all, because the fact that the amount of punitive damages is reasonable is going to vary in every case.

Senator STAFFORD. Mr. Corrin, do you think that the imposition of punitive damages and making an example of a manufacturer, for example, has improved or can improve the product?

Mr. CORRIN. Well, I think that that certainly is the goal of punitive damages, and I believe that if we look at some of the industries, we can see that it has had that effect.

I think if you look at the Dalkon Shield situation, it was known for a long time that the Dalkon Shield was causing serious damage to a lot of women, and it was finally taken off the market. But it was a long time between the time that it was taken off the market and the time that A.H. Robbins finally bit the bullet and said, "You had better take these things out if you are still wearing them." The main thing that changed during the time between when they stopped manufacturing and the time that they started recommending taking them out—well, actually, there were two things that happened. One was that they were hit with some punitive damage verdicts, and the other was that through the persistence of the lawyers that were representing the plaintiffs in those cases, information was developed that Robbins had been stonewalling and that they had been hiding information and destroying information that they were ordered by the courts to produce, and the combination of those two things is what caused them to finally take the last step and own up to the fact that if people did not take those things out that there were going to be more people injured as long as they were in use.

Senator STAFFORD. Mr. Corrin, let me ask you this question. Assuming, as some of the material in front of us seems to indicate, that the use of the vaccine, including the pertussis vaccine, there is

an actuarial probability of 1 case in 310,000 cases where the vaccines have been administered, and there has in consequence been a very low level of whooping cough or tetanus or the other for which it is being administered. And there is apparently a possibility that nobody will be willing to manufacture the vaccine in the light of possible liabilities.

Where do we go if, in spite of all the good this vaccine is doing, on the chance of one in 310,000, there will be some problems, where do we go if nobody will make the vaccine?

Mr. CORRIN. It depends on if there is a safer vaccine or not. I understand—at least some people say that the vaccine that is used in Europe is a safer vaccine than the vaccine that is used in the United States. If that is true, then there is not any problem. If that is not true, then maybe the Government has to bite the bullet and make the vaccine—I do not know. If there are not any elements of negligence involved, and there are not any elements of willful and wanton misconduct, then they have a lot less to worry about, especially in the area of punitive damages. But certainly, the people that are injured because of the fact that they do not get the warning that they could have, or something like that, should be entitled to recover. And we cannot take the 310,000th person and just say "To heck with him."

Senator STAFFORD. Well, thank you. I was posing the problem that I guess the country faces in this regard, all around.

Mr. CORRIN. Oh, I think that is right. I think that maybe with the polio vaccine, it is less of a problem because of the fact that actually, the live virus polio vaccine is the main cause of polio in the United States today; there is more of a risk from that than from not taking it.

Senator STAFFORD. Well, thank you very much.

[The prepared statement of Mr. Corrin follows:]

Dwight A. Corrin
December 9, 1985
Page 1

TO: COMMITTEE ON LABOR AND HUMAN RESOURCES

RE: VACCINE COMPENSATION (S.287)

MR. CHAIRMAN, SENATORS:

VACCINES PLAY AN IMPORTANT ROLE IN THE HEALTH OF OUR NATION, AND THEIR MANUFACTURE AND AVAILABILITY ARE OF CONCERN TO THE CITIZENRY. VACCINES SHOULD BE AS SAFE AS POSSIBLE, AND IF THEY POSE A RISK IN THEMSELVES, PERSONS EXPOSED TO THAT RISK ARE ENTITLED TO BE MADE AWARE OF IT. THIS IS PARTICULARLY TRUE WHEN THERE ARE STEPS AVAILABLE WHICH COULD REDUCE THE DEGREE OF RISK TO THE VACCINEE, OR TO OTHER MEMBERS OF THE PUBLIC.

ONE OF THE IMPORTANT ASPECTS OF OUR FORM OF GOVERNMENT IS OUR SYSTEM OF CHECKS AND BALANCES. I AM SURE THAT AS SENATORS YOU ARE ALL ACUTELY AWARE OF THE NEED TO PRESERVE THE ROLE OF THE LEGISLATIVE BRANCH ASSIGNED BY OUR FOUNDING FATHERS. THE JUDICIAL BRANCH AND ITS ROLE IS ALSO AN INTEGRAL PART OF OUR SYSTEM AND ONE OF THE MOST IMPORTANT ASPECTS OF THAT BRANCH IS THE EXISTENCE OF THE JURY. VERY FEW OF US EVER HAVE THE OPPORTUNITY TO RISE TO THE ROLE OF SENATOR, OR FOR THAT MATTER EVEN HAVE THE OPPORTUNITY YOU HAVE EXTENDED TO ME HERE TODAY TO ADDRESS A PORTION OF THAT BODY. VERY FEW OF US EVER HAVE THE CHANCE TO SERVE AS ELECTED OR APPOINTED OFFICERS IN ANY BRANCH OF THE FEDERAL GOVERNMENT, OR OF OUR RESPECTIVE STATES.

YET ANY ONE OF US MAY BE CALLED TO SERVE AS A JUROR, AND

FOR A BRIEF TIME PLAY A VERY IMPORTANT ROLE IN OUR GOVERNANCE. THIS INSTITUTION HAS BEEN AN IMPORTANT PART OF OUR COMMON LAW AND LEGAL TRADITION SINCE LONG BEFORE THE EUROPEAN SETTLEMENT OF NORTH AMERICA. IN MY STATE, KANSAS, OUR CONSTITUTION PROMISES THAT "THE RIGHT OF TRIAL BY JURY SHALL BE INVIOLATE." CONSTITUTION OF THE STATE OF KANSAS, BILL OF RIGHTS, § 5. SIMILARLY, THE SEVENTH AMENDMENT TO THE UNITED STATES CONSTITUTION PROVIDES THAT

> In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved.

THE LAW OF PRODUCTS LIABILITY HAS EVOLVED TO DEAL WITH THE FACT THAT MANY PRODUCTS WHICH HAVE BEEN PRODUCED AND MARKETED HAVE TURNED OUT TO BE UNREASONABLY DANGEROUS TO THE USER OR OTHER MEMBERS OF THE PUBLIC. THE RIGHT OF PERSONS INJURED BY SUCH PRODUCTS AND THE EXERCISE OF THAT RIGHT HAS RESULTED IN THE ELIMINATION OF MANY OF THESE DANGERS FROM THE MARKETPLACE.

WITHOUT THE RIGHT TO BRING SUIT AGAINST THE MANUFACTURERS OF DANGEROUS PRODUCTS, THE DANGERS OF SUCH PRODUCTS AS ASBESTOS, THE DALKON SHIELD, AND TAMPONS MADE OF FIBERS WHICH ENCOURAGED GROWTH OR ORGANISMS WHICH CAUSED TOXIC SHOCK SYNDROME. BIRTH CONTROL PILLS ARE OF LESS HAZARDOUS COMPOSITION BECAUSE OF PRODUCTS SUITS. THE FACT OF THE RISK OF SUITS AGAINST MANUFACTURERS OF VACCINES IF THEY DO NOT ACT RESPONSIBLY IN PROVIDING THE SAFEST VACCINES POSSIBLE, AND ALL THE INFORMATION WHICH MIGHT HELP PROTECT RECIPIENTS OR

CONTACTS OF RECIPIENTS OF THOSE VACCINES WILL FORCE THEM TO ACT RESPONSIBLY.

EMIL JOHNSON WAS A FARMER. HE FARMED ABOUT 500 ACRES OF LAND IN EASTERN KANSAS. HE TRIED TO ACT IN A SOCIALLY RESPONSIBLE MANNER, AND HE TOOK HIS DAUGHTER TO THE PEDIATRICIAN TO BE VACCINATED. NO ONE EVER TOLD HIM, OR HIS DAUGHTER'S DOCTOR THAT HE SHOULD CONSIDER BEING VACCINATED HIMSELF BEFORE HE HAD HIS DAUGHTER VACCINATED, BECAUSE HE OTHERWISE MIGHT GET POLIO. NO ONE TOLD HIM OR HIS DAUGHTER'S DOCTOR THAT MOST, IF NOT ALL, CASES OF POLIO OCCURRING IN THE UNITED STATES WERE CAUSED BY THE POLIO VACCINE HIS DAUGHTER WAS ABOUT TO RECEIVE.

THE EVIDENCE AT TRIAL WAS THAT IN 1968, SEVEN YEARS BEFORE EMIL JOHNSON CONTACTED POLIO WHEN HIS DAUGHTER RECEIVED THE VACCINE, RUSSELL F. CAHOON, M.D., AN EMPLOYEE OF LEDERLE LABORATORIES, SENT A MEMORANDUM TO EUGENE SWANZEY, M.D., WHO WAS THE DIRECTOR OF GOVERNMENT CONTROLS AT LEDERLE. DR. SWANZEY'S DEPARTMENT WAS CHARGED WITH THE RESPONSIBILITY OF COLLECTING AND CIRCULATING INFORMATION ABOUT THE VACCINE PACKAGE INSERT. DR. CAHOON WROTE DR. SWANZEY ABOUT THE FACT THE PACKAGE INSERT WAS NOT ADEQUATE. HE SUGGESTED

> spell[ing] out in detail in our package circular *all* of the facts reported by the Nat. C.D.C. Surveillance Committee with *added emphasis on the risk* and, in addition to advise the physician to so state such risk.

DR. SWANZEY'S RESPONSE TO THIS MEMO, ACCORDING TO HIS OWN

TESTIMONY, WAS TO WAD IT UP AND THROW IT IN THE WASTEBASKET. HE DID NOT SEE FIT TO CIRCULATE IT TO OTHER DOCTORS WITHIN LEDERLE LABORATORIES.

EMIL JOHNSON WAS ONLY A FARMER. HE IS NOT A BLUE BLOOD AND NOT A WORLDLY MAN. EVIDENTLY SOME PEOPLE HAVE THE ATTITUDE THAT MERE FARMERS AREN'T VERY IMPORTANT, AND DO NOT DESERVE A LARGE DAMAGE AWARD, NO MATTER HOW BADLY THEY ARE INJURED.

EMIL JOHNSON SUFFERS FROM TOTAL PERMANENT PARALYSIS OF HIS UPPER TRUNK, WHICH SIGNIFICANTLY IMPAIRS HIS BREATHING ABILITY. MOST OF US BREATHE WITHOUT EVEN GIVING IT MUCH THOUGHT. MR. JOHNSON MUST FIGHT FOR EVERY BREATH. SUFFOCATION OR LACK OF AIR IS SOMETHING I UNDERSTAND IS VERY FRIGHTENING. I AM VERY LUCKY AND HAVE NEVER BEEN IN A POSITION TO FIND OUT FIRST HAND JUST HOW BAD IT IS. I HAVE SEEN PEOPLE HAVING SERIOUS ASTHMA ATTACKS AND CERTAINLY WOULD NOT WANT TO STAND IN THEIR SHOES. EMIL JOHNSON CANNOT COUGH TO CLEAR HIS LUNGS, AND HE MUST USE MECHANICAL MEANS TO DO SO. HE HAS TO USE THE MAXI-MIST TO FORCE VAPOR AND DRUGS INTO HIS LUNGS EVERY FOUR HOURS, DAY AND NIGHT, AND MUCH MORE OFTEN WHEN HE HAS A COLD OR CONGESTION. MR. JOHNSON HAS TO TAKE STEROIDS DAILY, THEO-DUR AND BRETHINE, WHICH ARE BRONCHODIALTORS, HYDROCHLOROTHIAZIDE AND USES MAXI-MIST EVERY FOUR HOURS, WITH BRONKOSOL IN IT. HIS MEDICAL BILLS EXCEEDED $100,000.

EMIL JOHNSON WAS PARALYZED IN 1975, AND HAS YET TO BE COMPENSATED. HIS APPEAL IS SCHEDULED TO BE ARGUED IN JANUARY ON 1986. AN ADMINISTRATIVE PROGRAM TO COMPENSATE VACCINE VICTIMS WOULD BE WORTHWHILE IF, AND ONLY IF, IT DID NOT INFRINGE UPON THE RIGHT OF THE VICTIM TO HAVE ACCESS TO JUDICIAL REMEDIES, AND IF IT DID NOT FURTHER DELAY THE VICTIM'S ABILITY TO INITIATE JUDICIAL ACTION. ANY ADMINISTRATIVE PROGRAM SHOULD BE ESTABLISHED TO WORK QUICKLY, AND IN TANDEM WITH COURT ACTION, NOT AS A PREREQUISITE. THE ADMINISTRATIVE REMEDY SHOULD BE SIMPLE SPEEDY, AND THE AGENCY COULD BE REIMBURSED FROM ANY PROCEEDS EVENTUALLY RECOVERED FROM A MANUFACTURER OR PHYSICIAN OR OTHER TORTFEASOR WHO CONTRIBUTED TO THE INJURY. THE AGENCY SHOULD BE RESPONSIBLE FOR A PROPORTIONATE SHARE OF EXPENSES AND ATTORNEY'S FEES FOR THE AMOUNT RECOVERED FOR IT BY THE VICTIM AND HIS OR HER COUNSEL.

ANY ADMINISTRATIVE REMEDY ESTABLISHED SHOULD NOT BECOME A TRAP FOR THE UNWARY BY HAVING SHORT FILING DEADLINES. THERE SHOULD BE AMPLE TIME FOR THE VICTIM TO DISCOVER THE CAUSE OF HIS OR HER INJURY, AND DECIDE TO RETAIN COUNSEL, AND FOR COUNSEL TO INVESTIGATE BEFORE THE TIME TO FILE RUNS OUT. THE ADMINISTRATIVE REMEDY SHOULD NOT BE USED TO CIRCUMVENT AND SHORTEN STATE STATUTES OF LIMITATION FOR THE BENEFIT OF THE WRONGDOERS.

TO CREATE AN ADMINISTRATIVE AGENCY WHICH DEPRIVES A VICTIM OF ACCESS TO JUDICIAL REMEDIES WOULD BE WRONG FOR A NUMBER OF REASONS. IT WOULD TAKE AWAY THE ONE MEANS CITIZENS HAVE TO KEEP MANUFACTURERS HONEST. EXAMINATION OF THE HISTORY OF THE MOST WIDESPREAD PRODUCTS LIABILITY AREAS REVEAL A PATTERN OF INDUSTRY IGNORING KNOWLEDGE OF THE DANGER OF A PRODUCT.

THE ASBESTOS INDUSTRY, FOR EXAMPLE, KNEW AT LEAST BY THE 1930's THAT ASBESTOS FIBERS CAUSED SERIOUS LUNG DISEASE. YET IT WAS NOT UNTIL THE 1960's THAT ANY WARNING WHATSOEVER WAS EVER PASSED ALONG TO THOSE WHO WORKED WITH IT, AND THOSE WARNINGS WERE SO VAGUE THAT THEY DID NOT REFLECT THE REAL DANGER POSED BY THE PRODUCT.

THE MANUFACTURER OF THE DALKON SHIELD HAS BEEN FOUND TO HAVE DESTROYED DOCUMENTARY EVIDENCE AND MADE EVERY EFFORT TO PREVENT THE WOMEN WHO WERE VICTIM TO THAT PRODUCT TO FIND OUT ALL THE INFORMATION THEY HAD ABOUT ITS RISKS. THEY WAITED FOR YEARS BEFORE THEY FINALLY ADVISED DOCTORS AND WOMEN WHO WERE WEARING THE DALKON SHIELD THAT IS POSED A DANGER AND SHOULD BE REMOVED. WITHOUT THE JUDICIAL PROCESS, AND ITS ABILITY TO COMPEL PRODUCTION OF INFORMATION LOCKED AWAY IN COMPANY FILES, SOCIETY WOULD BE THWARTED MORE OFTEN IN ATTEMPTING TO FIND OUT THE REAL TRUTH ABOUT PRODUCTS.

THE RIGHT TO TRIAL BY JURY IS ONE OF THE MOST IMPORTANT

RIGHTS WE HAVE AS AMERICAN CITIZENS. REMOVING THIS IMPORTANT RIGHT WOULD BE A TRAVESTY OF THE HIGHEST ORDER. REPLACING IT WITH A RIGHT TO ACCESS TO A NEW GOVERNMENT BUREAUCRACY IS NOT A DESIRABLE SOLUTION. IN MOST AREAS OF GOVERNMENT, THE TREND IS TO DEREGULATION, AND TO LEAVING THINGS TO THE MARKETPLACE AND TO THE STATES. YET HERE TODAY WE ARE DISCUSSING A BILL WHICH WOULD REMOVE A RIGHT OF ACCESS TO THE JUDICIAL SYSTEM, WHICH HAS BEEN A PART OF THE MARKETPLACE SINCE OUR REPUBLIC WAS ESTABLISHED, AND TRANSFER AUTHORITY TO A FEDERAL AGENCY. WE ARE DISCUSSING A BILL WHICH WOULD TAKE AWAY THE ABILITY OF THE FIFTY STATES TO PROTECT THE HEALTH AND SAFETY OF THEIR CITIZENS, AND ASSIGN THAT RESPONSIBILITY TO A FEDERAL ADMINISTRATIVE PROGRAM. THIS BILL IS AN ASSAULT UPON THE CONSTITUTION OF THE STATE OF KANSAS, WHICH PROMISES THAT THE RIGHT OF TRIAL BY JURY IS INVIOLATE. THIS BILL IS AN ATTEMPT TO TAKE AWAY THE RIGHT OF THE PEOPLE OF THE STATE OF KANSAS, AND OF THE OTHER FORTY-NINE STATES, OF ACCESS TO THE COURTS OF THEIR STATES, AND OF A TRIAL BY A JURY OF THEIR PEERS, AND TO FORCE THEM TO LOOK TO A FEDERAL BUREAUCRACY FOR A REMEDY. IT IS A RADICAL PROPOSAL WHICH SHOULD NOT BE TOLERATED.

FINALLY, THERE IS A PROPOSAL TO IMPOSE A CAP UPON AWARDS FOR PAIN AND SUFFERING OR FOR PUNITIVE DAMAGES. SUCH CAPS ARE UNFAIR AND INEQUITABLE. CAPS UPON PAIN AND SUFFERING OPERATE TO PENALIZE THOSE MOST SERIOUSLY INJURED. IF AN INJURY IS RELATIVELY MILD, AND SHOULD REASONABLY BE COMPENSATED IN AN AMOUNT WITHIN THE AMOUNT OF THE CAP, THAT

RELATIVELY LIGHTLY HARMED PERSON IS NOT EFFECTED BY THE CAP. IT IS THE PERSON WHO IS MORE SERIOUSLY HARMED WHO HAS BEEN DEPRIVED OF THE FULL AWARD TO WHICH HE IS ENTITLED. IT IS THE PERSON WHO IS INJURED THE MOST WHO LOOSES THE MOST BECAUSE OF THE CAP.

EMIL JOHNSON MUST RETIRE WITH HIS MISTING EQUIPMENT SIX TIMES PER DAY TO DEAL WITH THE FLUID IN HIS LUNGS. WHO CAN SAY THAT EACH TIME HE MUST UNDERGO THIS OPERATION, HE IS NOT ENTITLED TO $1C FOR THE PAIN AND SUFFERING OF HAVING TO PERFORM AND SUFFER THROUGH THIS PULMONARY TOILET. IF WE ACCEPT THIS $100, WE FIND THAT HE WILL REACH THE CAP IN A MATTER OF LESS THAN FOURTEEN MONTHS. AND THAT IS ONLY ONE FACET OF HIS PAIN AND SUFFERING. EMIL JOHNSON SPENT 254 DAYS IN HOSPITAL FROM 1975 TO 1980. EVERY TIME HE DRAWS A BREATH, HE HAS TO FIGHT TO DO IT. CLIMBING A FLIGHT OF STAIRS IS HARDER FOR EMIL JOHNSON THAN RUNNING A MARATHON MIGHT BE FOR A WELL CONDITIONED LONG DISTANCE RUNNER. HE IS ALWAYS AT RISK FOR PNEUMONIA.

A CAP ON PUNITIVE DAMAGES WOULD DEFEAT THE WHOLE PURPOSE OF PUNITIVE DAMAGES. IN EMIL JOHNSON'S CASE, THE JURY AWARDED EIGHT MILLION DOLLARS, WHICH AT FIRST BLUSH MAY SOUND LIKE AN OUTRAGEOUS AMOUNT OF MONEY. IT AMOUNTS TO 0.226% OF THE NET SALES OF AMERICAN CYANAMID IN 1983, OR TO 0.262% OF THEIR NET ASSETS. THE PURPOSE OF PUNITIVE DAMAGES IS TO PUNISH THE DEFENDANT, AND TO SERVE AS AN EXAMPLE WHICH WILL

PREVENT THEM FROM REPEATING THEIR MISCONDUCT AND PREVENT OTHERS FROM ACTING IN A SIMILAR MANNER. IF PUNITIVE DAMAGES WERE LIMITED TO A FIXED SUM REGARDLESS OF THE SIZE OF THE WRONGDOER, THEY WOULD LOOSE THEIR EFFECT. A CAP OF $250,000 WOULD RESULT IN A MAXIMUM AWARD AGAINST AMERICAN CYANAMID IN THE AMOUNT OF 0.007% OF 1983 NET SALES, AND EVEN A CAP OF ONE MILLION DOLLARS WOULD AMOUNT TO 0.028% OF NET SALES. WHEN A CORPORATION HAS NET SALES OVER 3 AND ONE HALF BILLION DOLLARS, AN AWARD OF $250,000 WOULD HARDLY BE NOTICED, LET ALONE ENCOURAGE ANY CHANGE IN BUSINESS PRACTICES. THAT IS PROBABLY QUITE A BIT LESS THAN THE COST OF ADDING ONE MORE VICE-PRESIDENT TO THE PAY ROLL.

INTEROFFICE CORRESPONDENCE

Medical Controls Branch June 28, 1968

TO

ATTN OF Dr. Eugene Swanzey COPY TO

SUBJECT ORIMUNE POLIOVIRUS VACCINE
LIVE, ORAL

REFERENCE

Since the St. Louis Case, which was won by the Plaintiff in the sum of $160,000 and in which five of the jury members were in favor of the full award but were overruled, I have been giving this subject considerable thought. I can foresee that since no defendant Company has yet won a case, despite any defense, that with continued marketing of the Product for the indefinite future, wherein undoubtedly its primary use will be in its administration to the infant population and the adolescent group, that the very least we can expect may be a series of cases involving "vaccine-associated" cases in contacts of vaccinees. Even if general polio-vaccine programs of a community type may in the future be restricted in number, we may anticipate isolated cases of "vaccine-associated" disease in vaccinees.

The wording by which such cases are defined by the Advisory Committee and C.D.C. Surveillance Committee, to wit: "vaccine-associated" cases or categorized as "compatible with the possibility of having been induced by the vaccine", is in my opinion pure "semantics" and as evidenced by the judgments of the courts, amounts to no substantial defense. In addition, as you are well aware, the statement that the risk is no greater than one such case for three million doses of Orimune Poliovirus Vaccine administered, in the view of several courts, again is considered inadequately defensible.

The background briefly is as follows: In 1964, the Surgeon General Advisory Committee reviewed eighty-seven cases and considered fifty-seven of this number to be compatible with vaccine association and so reported. Since that time, the Neurotropic Viral Diseases Unit of C.D.C. has continued to use the criteria as established in 1964 in determining whether or not a case is "compatible."

According to the Annual Poliomyelitis Summary (1966) issued by the Nat. C.D.C. Surveillance Unit in Oct., 1967, five additional cases of paralytic disease were reported in persons receiving Orimune Poliovirus Vaccine, classified as "Vaccinees" in 1966, as well as five new such cases in 1964. In addition, this Report classifies twelve cases in the period 1965-1966 as "vaccine associated" in persons not having been given Orimune Poliovirus Vaccine but shown to have been "in contact" with recipients of Orimune Poliovirus Vaccine. This gives a total of eighteen "vaccine-associated" cases in the period of 1964-1966 in addition to the fifty-seven cases reported by the Advisory Committee in 1964. In this group

of eighteen cases, a total of thirteen virus-isolated had strain characterization studies completed. Twelve of these isolated were shown to be "vaccine-like" in character, only one was catalogued as a "wild type." Two additional cases of paralytic disease in "contacts with vaccinees" are reported in J.A.M.A., Sept. 4, 1967 and September 16, 1967, where a Type II strain was isolated from the patients who had been in contact with infants receiving Trivalent Orimuna Poliovirus Vaccine and characterized as "vaccine-like" strains.

Without doubt, other cases of similar nature have developed in the period 1967-1968 and are, as yet, unreported in the literature.

Curiously, the period of onset of paralytic illness in patients following vaccine administration is given as 4-30 days following feeding. In defining cases of paralytic illness in "contactees" an onset of such illness is extended to 60 days following feeding of the specific vaccine in question to the "vaccinee."

In summary, in my opinion, any defense based on the statements of the Advisory Committee or the Surveillance Committee of C.D.C. which is adhering to the criteria established by the Advisory Committee, is illusory. To state that any such paralytic illness in either a "vaccinee" or a "contactee" may be "vaccine-associated" or is "compatible with the possibility of having been induced by the vaccine" and that the laboratory data is not inconsistent with respect to the multiplication of the vaccine virus fed," is at best a weak position and difficultly defensible. I am sure no jury could understand nor accept what is in reality a "semantic" distinction.

With all of this coming to focus, I believe that our Company and all companies at present producing live poliovirus vaccines should review the problem immediately. We are all manufacturing the vaccine according to standards established by governmental agencies and have been indicating at least in reasonable fashion the risks involved, by our package labeling. Despite this, we have all been demonstrated as being extremely vulnerable to liability litigation and under the present circumstance, I cannot predict any protection in the future.

It would seem that one of the two courses or both may be available to give us better protection. The first is to spell out in detail in our package circular all of the facts reported by the Nat. C.D.C. Surveillance Committee with added emphasis on the risk and, in addition, to advise the physician to so state such risk. No doubt, many a prospective vaccines or his relative will be made less willing to accept the vaccine and this might reflect in reduced sales.

The more logical and sensible approach, is to arrange a common meeting with the appropriate personnal of the various manufacturers of poliovirus vaccines under the aegis of the P.M.A. to further consider the problem and to seek appropriate action with the government and/or Congress that would furnish the manufacturer with protection, either by establishment of a disclaimer of liability or some other effective measure. We are rendering a valuable service to the public but have no protection as to liability in those cases who risk and become the "1 case in 3,000,000

I have discussed the matter with Bert Lebeis very briefly already he tells me he is very much in favor of a claim along the lines I have given above.

Russell F. Cahoon, M. D.

RFC:dj

Senator STAFFORD. Dr. Shapo, we would be very pleased to hear from you.

Dr. SHAPO. Senator, I am Marshall S. Shapo. I am a professor at Northwestern University School of Law. I have submitted a prepared statement.

Senator STAFFORD. And we will place that in the record as if read, as we will, Mr. Corrin, for you and yours if you wish it, and you may summarize in any way you wish.

Mr. CORRIN. Yes, Senator, if you would.

Dr. SHAPO. As always, I find it a great privilege to be here. When I am here on these occasions, I cannot help thinking that my parents would have taken great satisfaction that their son was talking about the law with United States Senators.

I have to say that I have not mastered the specific data of the vaccine problem, so I am going to talk about this subject from the general perspective of one who has tried to describe how tort law works in the United States and to analyze the strengths and weaknesses of the so-called tort liability system.

I am going to refer to what I have learned in my specific study of product liability law, and I want to express my complete agreement with you, Senator, on the proposition that this is only one part of a more general set of questions that have arisen concerning that branch of the law.

I will say generally that as the main bill has been described to me, it would be a very unusual piece of legislation indeed. It provides for what one might call a regulated liability system and thus, I think, requires especially persuasive justification.

I think it is useful first to look at the subject from a fairly telescopic perspective, asking what the alternatives are that generally present themselves for dealing with injury victims in this society.

First, if we can identify a person or a firm that has caused an injury, we may for various reasons want to impose liability on that individual or firm. The polar alternative is to structure the law so that the injured person absorbs the loss. And I take it that there is general agreement that this is an unacceptable alternative in cases of the sort that the committee faces today. That is particularly so in the case of very young children who have absolutely no choice in the matter of whether they are to be vaccinated. You have used, Senator, the analogy of the sacrifice. I would say by further analogy that those injured by vaccines are effectively conscripts in a continuing battle for the public health.

A third possibility which is implied by what I have just said is that the Government might bear all or part of the cost of vaccine injuries. I take it that this controversy arises because of the assertedly ruinous expense of placing liability on the firms that produce the vaccines. Yet various courts have viewed vaccine makers as the appropriate place for the fixing of financial responsibility.

Even if we take as a given that there is nothing that can practically be done to improve the safety of vaccines, this result would have a certain ethical attractiveness to it, since the firm has after all profited from the sales of vaccines. It is worth emphasizing the obvious: If the production of vaccine were a nonprofit enterprise, market-oriented firms would not be producing it.

Moreover, while imposing liability might not raise the standard of conduct of manufacturers, a rule of nonliability would permit firms to profit without paying the costs inflicted by their activities.

It would seem that one thing that Congress would want to be very clear about in this situation is why it is that the price structure arguably will not permit the market to reflect the true social cost of a product that everyone needs.

Is there a peculiarity in the business of insuring vaccine injuries that has produced a situation in which the market prices required by tort liability would cause the public health to suffer, or that would require disadvantaged persons to undergo extra privation in order to provide vaccine for their children? I assume that it is asserted that this is the situation which exists; yet even if that is so, it would not by itself argue for reducing the burden of judicially-assessed financial responsibility borne by vaccine makers.

At the same time, because of the fact that the need for vaccine is tied in closely with the public health, there is something to be said for involving the Government in the process of compensating those injured by vaccines. If this were not so, it would be difficult to argue that the Government should single out this particular enterprise for this sort of treatment.

Given that it is so, one might rationally decide that the burden of vaccine injuries should be redistributed from that which the law now imposes.

In part, the current controversy concerns the question of whether and how much of that burden should be borne by the injured persons themselves. Perhaps it is time to employ a different noun. One should say by the injured "victims" themselves. I have deliberately avoided using that emotionally laden word to this point, but I use it now to emphasize the fact that once a court calculates damages according to law, any limitation on that figure leaves the victim to bear those costs—costs that our legal system has historically chalked up, for example, under the headings of damages for wrongful death and for pain and suffering. I am not necessarily saying that Congress could not rationally make that determination. What I am emphasizing is that there should be full recognition of the implications of requiring victims to risk that burden by making an election.

This leads me to a few concluding observations. First, while I have not made myself expert in the data concerning this particular problem, I am very much concerned about the passage of legislation that both makes substantive changes in the law and at the same time sets up an inquiry into the facts on which legislation ought to depend. This bill, now that I have had an opportunity at least to scan it, is a remarkable example. It sets on foot as many as five separate investigations of legislative facts.

I would add that legislation which creates exceptions to basic tort rules with major questions left unanswered is likely to invite constant controversy and amendment. The result may well be to return in the direction of the original state of the law.

I note that what I have said here surely applies to variations on the basic idea that claimants should be required to make the sort of election which I understand to be proposed by S. 827. It seems to

me that a heavy burden rests on one who would single out a particular industry for that sort of treatment.

Moreover, I would point out that the general workings of tort law have historically provided a method of dispute resolution which is more consensual. It was pointed out by the report of the ABA's Special Committee on the Tort Liability System, for which I served as reporter, that defendants may always offer, and claimants are always free to accept, prompt payment for the relief of injury.

These remarks do not suggest that the present tort system is exclusively the best one for this unusual problem. It may be that because of its public health implications, this is one of the very special cases where for reasons of justice, it would be desirable to modify the existing judge-made rules in some way.

I do not believe, however, that the main bill presents a desirable alternative. I have simply not had time to prepare formal comments on the many weaknesses, inconsistencies and demands for explanations that even my summary reading of the bill reveals. At the very least, the alternative system proposed by the bill requires us to ask what role is envisioned for the Government; is it to be a statistician for industry? A surrogate receiver? An insurer? A guarantor? A subsidizer, in a day when subsidies receive increasing skepticism?

I would close by emphasizing that one should not underestimate the resilience of tort law or indeed its ability to represent what Americans think of as the just result. In that regard, as it says in the ABA report, if tort law did not exist, we would invent it or reinvent it.

In fashioning a legislative response to this heart-rendingly sympathetic situation, I think it important that Congress keep in mind the social goals that our law of injuries generally reflects.

Thank you very much, Senator.

Senator STAFFORD. Thank you very much, Dr. Shapo.

[The prepared statement of Mr. Shapo follows:]

LIABILITY AND COMPENSATION FOR VACCINE INJURIES

Testimony of Professor Marshall S. Shapo
to Committee on Labor and Human
Resources.

United States Senate, 9 December 1985.

Mr. Chairman, I am Marshall S. Shapo. I am a professor of law at Northwestern University School of Law. I have been teaching about the subject of Torts and related matters for more than twenty years, and for a good part of that time I have specially studied the law of products liability. From 1980 to 1984 I was the Reporter for the Special Committee on the Tort Liability System of the American Bar Association. I appear here, however, representing only my own views.

I shall speak about this subject from the general perspective of one who has tried to describe how tort law works in the United States, and to analyze the strengths and weaknesses of the so-called tort liability system. Unfortunately, given the erratic quality of the mail as well as a pre-determined travel schedule over the last few days, I have had to form these thoughts before looking at the bills that are before the Committee.

I will say generally that as the main bill has been described to me, it would be a very unusual piece of legislation indeed. It provides for what might be called a regulated liability system, and thus requires especially persuasive justification.

I think it is useful first to look at the subject from a telescopic perspective: What are the alternatives that generally present themselves for dealing with injury victims in this society?

First, if we can identify a person or firm who has caused an injury, we may for various reasons wish to impose liability on that individual or firm.

A polar alternative is to structure the law so that the injured person absorbs the loss. I take it there is general agreement that this is an unacceptable alternative in cases of the sort that the Committee faces today. This is particularly so in the case of very young children, who have absolutely no choice in the matter of whether they are to be vaccinated. More generally, those injured by vaccines are effectively conscripts in the continuing battle for the public health.

A third possibility, implied by what I have just said, is that the Government might bear all or part of the cost of vaccine injuries.

As we review these basic possibilities, I take it that the controversy arises because of the assertedly ruinous expense of placing liability on the firms that produce the vaccine. Yet various courts have viewed vaccine producers as the appropriate place for the fixing of financial

responsibility. Even if we take as a given that there is nothing that can practically be done by manufacturers to improve the safety of vaccines, this result has a certain ethical attractiveness to it, since the firm has, after all, profited from the sales of vaccine. It is worth emphasizing the obvious: if the production of vaccine were a non-profit enterprise, market-oriented firms would not be producing it. Moreover, while imposing liability might not raise the standard of conduct of manufacturers, a rule of non-liability would permit firms to profit without paying the costs inflicted by their activities.

It would seem that one thing that Congress would want to be very clear about in this situation is why it is that the price structure will not permit the market to reflect the true social cost of a product that everyone needs. Is there a peculiarity in the business of insuring vaccine injuries that has produced a situation in which the market prices required by tort liability would cause the public health to suffer? Or that would require disadvantaged persons to undergo extra privation in order to provide vaccine for their children? I assume it is asserted that this is the situation which exists. Yet even if that is so, it would not by itself argue for reducing the burden of judicially assessed financial responsibility borne by

vaccine makers.

At the same time, because of the fact that the need for vaccine is tied in closely with the public health, there is something to be said for involving the Government in the process of compensating those injured by vaccines. If this were not so, it would be difficult to argue that the Government should single out this particular enterprise for this sort of treatment. Given that it is so, one might rationally decide that the burden of vaccine injuries should be redistributed from that which the law now imposes.

In part, the current controversy concerns the question of whether, and how much, of that burden should be borne by the injured persons themselves. Perhaps it is time to use a different noun: One should say by the injured victims themselves. I have deliberately avoided using that emotionally laden word to this point. But I use it now to emphasize the fact that once a court calculates damages according to law, any limitation on that figure leaves the victim to bear that cost. I am not necessarily saying that Congress could not rationally make that determination. What am emphasizing is that there should be full recognition of ıe implications of requiring victims to risk that burden by king an election.

This leads me to a few concluding observations. First,

while I have not made myself expert in the data concerning this particular problem, I am very much concerned about the passage of legislation that both makes substantive changes in the law and at the same time sets up an inquiry into the facts on which legislation ought to depend. I would add that legislation which creates exceptions to basic tort rules, with major questions left unanswered, is likely to invite constant controversy and amendment. The result may well be to return in the direction of the original state of the law.

I note that what I have said here surely applies to variations on the basic idea that claimants should be required to make the sort of election which I understand to be proposed by S. 827. It seems to me that a heavy burden rests on one who would single out a particular industry for that sort of treatment. Moreover, I would point out that the general workings of tort law have historically provided a method of dispute resolution which is more consensual. As the Report on which I worked for the ABA Special Committee pointed out, "defendants may always offer, and claimants are always free to accept, prompt payment for the relief of injuries."

These remarks do not suggest that the present tort solution is exclusively the best one for this unusual

problem. It may be that because of its public health implications, this is one of the very special cases where for reasons of justice, it would be desirable to modify the existing judge-made rules in some way. I do not believe, however, that the main bill presents a desirable alternative.

I would close by emphasizing that one should not underestimate the resilience of tort law, or indeed its ability to represent what Americans think of as the just result. In that regard, as it says in the ABA Report: "If tort law did not exist, we would invent it -- or re-invent it." In fashioning a legislative response to this heartrendingly sympathetic situation, I think it important that Congress keep in mind the social goals that our law of injuries generally reflects.

Senator STAFFORD. Now, Mr. Anthony Colantoni, we will be very happy to hear from you.

Mr. COLANTONI. Thank you, Senator.

My name is Anthony Colantoni, and I am an attorney in the firm of McDowell & Colantoni in Chicago. Our law firm presently represents approximately 175 children, adults and families who have suffered injury as a result of immunization with diphtheria, tetanus and pertussis vaccine.

I, too, would like to commend this committee and its members and staff for their tireless efforts to search for a solution to a problem which is national in scope. The issue of how best to compensate victims of vaccine injury, promote the development of a safe vaccine, assure adequate levels of vaccine supply and maintain the integrity of our national immunization program has no easy answer. It is through this very worthy legislative process that all interested parties have the opportunity to present their views and participate in discourse with an eye toward resolution.

This committee has promised enlightened legislation, and this hearing is yet another example of its intention to keep its word.

In considering the controversy surrounding DPT vaccine and Senate bill 827, I operate from one simple truth. That is that the manufacturers of DPT in the United States have continued to produce their products despite their knowledge for at least a quarter of a century that this vaccine causes serious adverse neurological reactions in our children and despite their ability for at least 20 years to make a safer, less toxic vaccine.

I have seen the in-house reports and I have seen the interoffice memoranda, and the evidence is clear and overwhelming in that regard. As an attorney who represents vaccine-damaged children, I cannot divorce myself from that fact. Thus, in my opinion, the problem and any potential solution must be viewed against this backdrop.

The desirability of any administrative program to compensate vaccine victims hinges on whether it supplements or supplants the right of each victim to have his day in court as guaranteed by the seventh amendment to the United States Constitution.

The traditional remedy of civil litigation has served us well, and we should not now be bullied or misled into turning our backs on it. Many statements offered in past hearings by interested members or interested parties concerning the failures of the tort system are simply not true.

For example, manufacturers claim that there is no protection against the filing of frivolous lawsuits, a practice which they urge increases costs and adds to the difficulty of obtaining liability insurance. Yet the very nature of DPT litigation dictates against the initiation of groundless claims.

My firm anticipates expenses in excess of $100,000 per suit for claims brought on behalf of vaccine-damaged children. The suits that are filed go through a very careful screening process, so that we are absolutely convinced from both legal and medical perspectives that the child's injury was causally related to the vaccine. Setting aside for the moment our belief that it is our moral and professional responsibility to present to the court only legitimate

claims, it would be financial suicide to attempt to prosecute a case not supported by fact or law.

It is obvious to even the casual observer that the pharmaceutical industry is using the same type of argument employed by medical groups and the insurance industry to support restrictions on medical malpractice claims. In this instance, however, it is even more vivid that the circumstances of DPT litigation simply do not support this contention. What is truly frivolous is the suggestion that they do.

Representatives of the pharmaceutical industry and others suggest that excessive litigation and excessive jury awards are the most important factors in the decline of vaccine production. This assertion is made in support of the claim that litigation in this area is doing no one any good and should best be replaced in toto by an administrative scheme.

Note, however, that it is not the victims of wrongful conduct but rather the wrongdoers themselves who at first complain of the alleged inadequacies of the tort system and then clamor to cut off the ability of the injured party to be compensated by the one who caused the injury.

Again, we must turn to the one simple truth mentioned earlier. A drug manufacturer who knowingly produces an unreasonably dangerous defective vaccine or who is negligent in the manufacture of that vaccine must be held accountable when the vaccine causes injury. The principles underlying this truth have been with us for hundreds of years and serve as a cornerstone of our democratic society.

Our system of civil litigation is unique in its ability to respond to the needs of the injured party by shifting the burden of the cost of injury off the shoulders of the innocent victims and onto those who are both responsible for the injury and best able to bear its costs.

Perhaps the tort system is not always as efficient or as businesslike as some would wish. But the function of the system is neither efficiency nor business. The function of the tort system is to ferret out the truth and to deliver just compensation when called for, and it works admirably in that regard.

While S. 827 as currently drafted appears on paper to spare the system from any harmful changes, it is not without its problems, especially in light of its avowed purpose to provide "just compensation to children and other individuals who have sustained vaccine-related injuries." The system of election of one remedy, either a compensation program or civil suit, and waiver of the other places victims and their families in the throes of a dilemma.

Do they choose the administrative program or do they opt for civil suit? The compensation system at first blush appears to have its advantages. A claimant's burden of proof is eased somewhat in that he need not demonstrate negligence or defective product, and there is provided a schedule of compensable injuries. Yet he may be required to go through a hearing, respond to the challenge of expert witnesses, deal with cross-examination, and he ultimately places his future in the hands of one person. Then, there can be a de novo determination by the trial court and an appeal by the government. And this is not without cost or expense to the claimant. Moreover, he is limited in the amount he can recover for his pain

and suffering, and he may very well foreclose the rights of his family to receive compensatory damages under existing State laws.

On the other hand, if he chooses to file a civil suit and waives his right to an administrative remedy, he must face an admittedly longer and more costly procedure in the hopes of obtaining full compensation. I would submit that the scheme of election and waiver may place an additional unfair burden on an innocent injured party already once victimized.

Senator Stafford's alternative proposal, which requires entry into the administrative program as a prerequisite to pursuing civil remedies, seems to resolve this dilemma. It more closely achieves S. 827's goal of an expedited, no-fault and effective program for just compensation. It does this by providing for some financial support to ease the burdens of some families, while at the same time allowing them to seek full compensation in a court of law. However, it too is not without its difficulties since it necessarily adds 9 months onto the length of the entire litigation process.

Further, I feel compelled to point out that any prerequisite administrative program will have a chilling effect on subsequent civil litigation. It should come as no surprise that a claimant who has prevailed in the administrative program may decide to forego civil remedies at his disposal. He has been compensated, although perhaps not as much or to the degree possible via the tort system, but this compensation has not come without its price. It has taken 9 months or longer if he chooses to receive an award.

There has been, in all likelihood, out-of-pocket cost associated with the prosecution of this claim. One or more of his family has been subject to cross-examination under oath, a traumatic experience for many people. Finally, that the entire process has exacted a heavy toll on the emotional climate and stability of the family unit cannot be questioned.

Given this scenario, it is not difficult to imagine a claimant passing up the opportunity to seek compensation through litigation. I submit that this may turn the administrative program into an exclusive remedy, something which we can ill afford to do if we desire the safest vaccine possible at any given time.

Any provision which tampers with the rights of innocent victims to receive just compensation from vaccine manufacturers in a civil suit must be flatly rejected. To suggest, as some have, that awards for pain and suffering or punitive damages should be limited to a certain dollar amount or prohibited altogether is to add insult to injury in the literal sense. The goal of just compensation is to place the victim in as close a position as he would have been had the injury not occurred.

Awards for past medical expenses and medical expenses reasonably expected to be incurred in the future are nothing more than dollar-for-dollar reimbursements. So too are damages for lost wages reasonably expected to be earned in the future.

Pain and suffering is a traditional element of damages because it is a natural consequence of physical injury. A child who is mentally retarded or who develops a seizure disorder as a result of DPT immunization experiences both pain and suffering. The amount is dependent upon a variety of factors including the severity and du-

ration of the injury. What is clear also is that this amount varies from case to case.

To now set arbitrary limits assures that some victims will not be fully compensated, a result which flies in the face of S. 827's purpose to provide just compensation to all who have sustained vaccine-related injuries. Such a limitation cannot be accepted because it again rewards industry inaction and negligence at the expense of entirely innocent children.

An award of punitive damages, on the other hand, serves a different purpose. It finds its basis in public policy considerations and is given when a wrongdoer shows an utter indifference to or conscious disregard for the safety and well-being of others and causes injury.

It serves to punish a defendant for such outrageous conduct and to deter him and others from the commission of like offenses. Sometimes it is not enough to require a tortfeasor to simply pay for the injuries naturally flowing from his conduct. There are occasions when the conduct is so indifferent to or contemptuous of the rights and safety of others that more is needed. A penalty must be levied.

Limitations on the amount of damages one must pay effectively reduces the threat of such a penalty. A limitation does not promote socially acceptable conduct but rather, it provides a potential wrongdoer with the ability to calculate with certainty damages as a cost of doing business and then engage in a course of conduct, well knowing that he will have to pay only so much. We cannot expose our children to the additional risks such limitations will pose. They have already sustained too many injuries because it is less expensive or it is expedient to make the current whole cell vaccine than it is to engage in research and development or in the production of a safer vaccine.

And Senator, I would like to depart from my prepared comments to discuss Senator Dodd's amendment. I have not seen a proposed draft of that amendment, but I think we should all view with suspicion any amendment which requires or which allows compliance with any Federal regulation as an affirmative defense in a civil suit, for several reasons. I think the first and foremost is the fact that the current regulations which exist have been developed over the past 30 years in unison with government cooperation and industry cooperation. The industry has had much to do, perhaps the majority of responsibility, in developing the regulations, and they have failed miserably in that regard.

We know, as the industry does, that the mouse toxicity test bears no reasonable clinical relationship to injuries in children. We know that the potency test that exists under the Federal regulations is not totally suited to the needs of a proper vaccine.

The stamp of approval that the Bureau of Biologics gives on an insert that accompanies the warnings is another curious regulation, and if I may, I would like to read the stamp that is currently placed on all inserts that accompany the DPT vaccine in particular. It reads as follows:

Not inconsistent with biological control provisions of Public Health Service Act, or with Federal Food, Drug and Cosmetic Act, and regulations issued thereunder, except as noted. Review does not indicate either approval or disapproval of any rep-

resentations made with respect to this product that may be material under any other applicable statutes or regulations.

I think it is clear that the regulations as developed are minimum requirements. For 17 years, they were termed "minimum" requirements of production vaccine, and there is no guarantee that we get the safest vaccine possible from those minimum requirements.

Moreover, I believe in every jurisdiction that I am involved in, evidence of compliance with Federal regulations or standards is some form of defense in civil litigation, so that we are not really adding that much, except perhaps giving the imprimatur of this body by saying now that it would be an affirmative defense. They are allowed in almost every jurisdiction throughout the country, as I understand it.

The way to rebut that evidence, of course, is to demonstrate that the vaccine is not as safe as possible. And unless we have requirements that call for state-of-the-art vaccines, and unless those regulations are updated on as frequent a basis as possible, we are not going to have the safest vaccine possible at any given time.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Colantoni and responses to questions subsequently submitted by Senator Hatch follow:]

TESTIMONY

BEFORE THE

UNITED STATES SENATE

COMMITTEE ON LABOR AND HUMAN RESOURCES

ON

SENATE BILL 827,

THE NATIONAL CHILDHOOD VACCINE INJURY COMPENSATION ACT OF 1985

PRESENTED BY

ANTHONY M. COLANTONI, ESQ.

DECEMBER 9, 1985

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My name is Anthony M. Colantoni. I am an attorney from Chicago, Illinois. My Law Firm presently represents approximately 175 children, adults and families who have suffered injury as a result of immunization with Diptheria-Tetanus-Pertussis vaccine. On behalf of my clients, I commend this Committee, its members and staff, for their tireless efforts to search for a solution to a problem that is national in scope, catastrophic in effect. The issue of how to best compensate victims of vaccine injury, promote the development of a safe vaccine, assure adequate levels of vaccine supply and maintain the integrity of our national immunization program has no easy answer. It is through this very worthy legislative process that all interested parties have the opportunity to present their views and participate in discourse with an eye toward resolution which addresses the needs of all concerned. This Committee has promised enlightened legislation and this hearing is yet another example of its intention to keep its word.

In considering the controversy surrounding DPT vaccine and Senate Bill 827, I operate from one simple truth. The manufacturers of DPT vaccines in the United States have continued to produce their products despite their knowledge for at least a quarter of a century that this vaccine causes serious adverse neurological reactions in its recipients and despite their ability for over twenty years to make a safer, less toxic vaccine. I have seen the in-house reports and the inter-office memos and the evidence is clear and overwhelming in that regard. As an attorney who represents vaccine damaged children, I cannot divorce myself from that fact. Thus, in my opinion, the problem and potential solutions must be viewed against this backdrop.

The desirability of an administrative program to compensate vaccine victims hinges on whether it supplements or supplants the right of each victim to have his day in court as guaranteed by the Seventh Ammendment to the United States Constitution. The traditional remedy of civil litigation has served us well and we should not now be bullied or misled into turning our backs on it. Many statements offered in past hearings by members of the medical community and the pharmaceutical and insurance industries concerning the failure of the tort system to respond to the needs of vaccine injured children are simply not true. For example, it does not take six to eight years for a suit to reach its conclusion, as has been suggested by some parties. My experience shows that many dockets throughout the country are running at a pace of about eighteen months from the time of filing a lawsuit to the time of trial and you need only go to the United States District Court For the Northern District Of Virginia in Alexandria to find a five month docket.

Manufacturers claim that there is no protection against the filing of frivilous lawsuits, a practice which they urge increases their costs and adds to the difficulty of obtaining liability insurance. Yet, the very nature of DPT litigation dictates against the initiation of groundless claims. My firm anticipates expenses in excess of $100,000.00 per suit brought on behalf of a vaccine damaged child. The suits that are filed go through a very careful screening process so that we are convinced from both legal and medical perspectives that the child's injury was causally related to DPT immunization and are satisfied that the injuries suffered are severe enough to justify the expenditure of time and money. Setting aside for

the moment our belief that it is our moral and professional responsibility to present to the court only legitimate claims, it would be financial suicide to attempt to prosecute a case not supported by fact or law. It is obvious to even the casual observer that the pharmaceutical industry is using the same argument employed by medical groups and insurance industries to support restrictions on medical malpractice cases. In this instance, however, it is even more vivid that the circumstances of DTP litigation simply do not support this contention. What is truly frivolous is the suggestion that they do.

Representatives of the pharmaceutical industry and others suggest that excessive litigation and excessive jury awards are the most important factors in the decline of vaccine production. This assertion is made in support of the claim that litigation in this area is doing no one any good and thus should be replaced in toto by an administrative scheme. It is immediately apparent that it is not the victims of wrongful conduct but rather the wrongdoers themselves who at first complain of alleged inadequacies of the present tort system and then clamor to cut off the ability of an injured party to be compensated by the one who caused the injury. Again, we must turn to the simple truth mentioned earlier. A drug manfacturer who knowingly produces an unreasonably dangerous defective vaccine or who is negligent in the manufacture of that vaccine must be held accountable when the vaccine causes injury. The principles underlying this truth have been with us for hundreds of years and serve as a cornerstone of our democratic society. Indeed, our system of civil litigation is unique in its ability to respond to the needs of the injured party by shifting the

burden of the cost of injury off the shoulders of the innocent victims and on to those who are both responsible for the injury and best able to bear its costs. Perhaps the tort system is not always as efficient or as business-like as some would wish. But the function of the system is neither efficency nor business. The function of the tort system is to ferret out the truth and to deliver just compensation when called for, and it works admirably in that regard.

Another effect of our system of civil litigation, which is of paramount significance and benefit, is its ability to reach the problem of the defective or negligently made vaccine at the only point where prevention of unnecessary future injuries is possible. The constant threat of civil litigation provides ample stimulus for manufacturers to develop a better, safer product. It is no coincidence that the recent surge in acellular pertussis vaccine research comes in the wake of large settlements and jury verdicts against vaccine manufacturers for injuries caused by their defective products. The record of this industry demonstrates that its members sat idly by for years until forced into action by successful claimants. Then, given the realization that they could no longer avoid responsibility for their negligence and the manufacture of an unreasonably dangerous defective product, individual manufacturers began to engage in the research and development of a new vaccine. Any legislation which removes this impetus, or effectively insulates the industry from this powerful threat by granting new defenses, will do nothing less than send the message that years of inaction will be rewarded by immunity from legal responsibility and guarantee continuation of the status quo. Too many

children and families have suffered far too much pain and devastation to allow this to happen now.

While S.827 as currently drafted appears to spare the tort system from any harmful changes, it is not without its problems, especially in light of its avowed purpose to provide "just compensation to children and other individuals who have sustained vaccine related injuries." I speak directly of Sections 2102(b) and (c) (1). The system of election of one remedy, either a compensation program or civil suit, and waiver of the other, places victims and their families in the throws of a dilemma. Do they choose the administrative program or opt for civil suit? The compensation system, at first blush, appears to have its advantages. A claimant's burden of proof is eased somewhat in that he need not demonstrate negligence or defective product and there is provided a schedule of compensable injuries. Yet, he may be required to go through a hearing, respond to the challenge of expert witnesses, deal with cross-examination and he ultimately places his future in the hands of one person. Then, there can be a de novo determination by the court and an appeal by the government. And this is not without cost or expense to the claimant. Moreover, he is limited in the amount he can recover for his pain and suffering, and he may very well foreclose the rights of his family to receive compensatory damages under existing state laws. On the other hand, if he chooses to file a civil suit and waives his right to an administrative remedy, he must face an admittedly longer and more costly procedure in the hopes of obtaining full compensation. In my opinion, this scheme of election and waiver places an additional unfair burden on an innocent injured party already once victimized.

Senator Stafford's alternative proposal, which requires entry into the administrative program as a prerequisite to pursuing civil remedies, seems to resolve this dilemma. It more closely achieves S.827's goal of an expedited, no-fault and effective program for just compensation. It does this by providing for some financial support to ease the burdens of some families, while at the same time allowing them to seek full compensation in a court of law. It too is not without its difficulties, since it necessarily adds nine months on to the length of the entire litigation process. In the case of a family who has had the good fortune and the good sense to purchase insurance policies which cover all or most of the expenses listed under Section 2107 (a) (1) (A), this mandatory filing may serve no purpose other than to delay ultimate resolution of the claim by nine months.

Further, it is very possible that a prerequisite administrative program will have a chilling effect on subsequent civil litigation. It should come as no surprise that a claimant who has prevailed in the administrative program may decide to forego the civil remedies at his disposal. He has been compensated, although perhaps not to the degree possible via the tort system, but this compensation has not come without its price. It has taken nine months, or longer if he chooses to receive an award. There has been, in all likelihood, out of pocket costs associated with the prosecution of the claim. One or more of his family has been cross-examined under oath, a traumatic exprience for many people. Finally, that the entire process has exacted a heavy toll on the emotional climate of the entire family unit cannot be questioned. Given this scenario, it is not difficult to imagine a claimant passing up the opportunity to seek compensation through litigation.

I submit that this may turn the administrative program into an exclusive remedy, something we can ill afford to do if we desire the safest vaccine possible at any given time.

Any provision which tampers with the rights of innocent victims to receive just compensation from vaccine manufacturers in a civil suit must be flatly rejected. To suggest, as some have, that awards for pain and suffering or punitive damages should be limited to a certain dollar amount or prohibited altogether is to add insult to injury in the literal sense. The goal of just compensation is to place the victim in as close a position as he would have been had the injury not occurred. Awards for past medical expenses and medical expenses reasonably expected to be incurred in the future are nothing more than a dollar for dollar reimbursement. So too are damages for lost wages reasonably expected to be earned in the future. Pain and suffering is a traditional element of damages because it is a natural consequence of physical injury. A child who is mentally retarded or who develops a seizure disorder as a result of DTP immunization experiences both pain and suffering. The amount of pain and suffering is dependent upon a variety of factors including the severity and duration of the injury. What is clear also is that this amount varies from case to case. To now set arbitrary limits assures that some victims will not be fully compensated, a result which flies in the face of S. 827's purpose to provide just compensation to all who have sustained vaccine-related injuries. Such a limitation cannot be accepted because it again rewards industry inaction and negligence at the expense of entirely innocent children.

An award of punitive damages, on the other hand, serves a

different purpose. It finds its basis in public policy considerations and is given when a wrongdoer shows an utter indifference to or conscious disregard for the safety and well being of others, and causes injury. It serves to punish a defendant for such outrageous conduct and to deter him and others from the commission of like offenses. Sometimes it is not enough to require a tortfeasor to simply pay for the injuries natually flowing from his conduct. There are occasions when the conduct is so indifferent to or contemptious of the rights and safety of others that more is needed. A penalty must be levied.

Limitations on the amount of punitive damages one must pay effectively reduces the threat of such a penalty. A limitation does not promote socially acceptable conduct. Rather, it provides a potential wrongdoer with the ability to calculate with certainty punitive damages as a cost of doing business and then engage in a course of conduct well knowing that he will have to pay only so much. We cannot expose our children to the additional risks such limitations will pose. They have already sustained too many injuries because it is less expensive or expedient to make the current whole cell vaccine than it is to engage in research and development or in the production of a safer product.

While there is a need to foster a suitable climate for the continued development and production of childhood vaccines, we cannot ignore the plight of perhaps thousands of citizens who have suffered injury. We cannot refuse full and fair compensation where fact and law demonstrate that they are entitled. Any such proposals must be carefully reviewed and re-examined with a view toward a system which responds with compassion and justice rather than immunity for the continued production of an unsafe vaccine. For this national concern, we cannot afford a legislative solution which does not recognize the foregoing and which allows our children only a partial measure of compensation and protection.

RESPONSE TO QUESTIONS SUBMITTED BY SENATOR HATCH

1. Do you believe that fear of losing lawsuits encourages research into newer and safer products?

RESPONSE: It is my firm belief that the threat of paying money damages to persons injured by a product is a major impetus to the manufacturer of that product to remove the cause of such injury if it wishes to stay in business. This is especially true if the cause of the injury can be removed for a small fraction of the total cost of the product and a miniscule amount compared to the cost of a lawsuit. For example, International Harvester vented their tractor gas caps to avoid explosion at very little cost, in response, in part, to lawsuits filed for injuries caused by such explosions. Punch-press machines, historically the subject of lawsuits, now have safety gates and emergency power cut-offs in response to the thousands of injuries caused by machines lacking those features.

With regard to the manufacture of DTP vaccine, I urge that the Senator to examine the history of American vaccine makers' current efforts to make a safe vaccine. I'm confident you'll find that manufacturer's here are five to seven years behind the Japanese research, production and distribution of an acellular DTP vaccine.

This time lag doesn't relate to a technology gap, for certainly American manufacturers possess the same skill, ability and knowledge as their foreign counterparts. I suggest that this time lag can be traced directly to the growing public awareness of the problems associated with the American DTP vaccine and the increase in the number of lawsuits brought by victims of the vaccine. The increase in research and development at a time when the numbers of reported injuries have risen substantially tells a disappointing tale of an industry pushed into action only when it realizes the high cost - in terms of lives, human productivity and money - of its inaction.

Perhaps more revealing, however, is the information gleaned through the litigation discovery process. In company documents, memos and reports we have seen time after time that the manufacturers have unlocked some of the secrets of bordetella pertussis, developed in the laboratory a less reactive vaccine and the made the corporate decision to forego further development, production and distribution because of the costs involved. While these companies come before you now and offer statement of sincerity and concern for infants as evidence of their corporate morality their documents demonstrate the opposite. Two conclusions are inescapable. First, these companies are more concerned with the bottom line rather than the quality of their product. Second, unless forced into action by lawsuits which hit them in the place when it hurts the most, they'll do nothing.

2. Is it possible that fear of lawsuits actually discourages companies from investing in new products?

RESPONSE: It is entirely possible that fear of costs associated with lawsuits discourages companies from investing in new products. However, I urge this Committee that when you have lives in the balance, this can be no concern at all. We're talking about death and brain damage from a product which can and must be made safer and we must not act out of concern for corporate profits at the expense of innocent victims. I realize that this is not a popular position but given the realities of the situation it is the only position we can take. If companies do drop out of the market, others who have the capacity and desire will fill the void. This basic fact of supply and demand has happened before and it will happen again.

It is also paradoxical that the same manufacturers who say they're concerned with the health and welfare of our children threaten in the next breath to withdraw from the market and place these same children at risk from whooping cough unless they receive protection from lawsuits. This attitude has pervaded their thinking from the very outset and unmasks their true concerns. It is further evidence that our concern must be for our children and not for a few corporate bank accounts.

Senator STAFFORD. Thank you, Mr. Colantoni.

I am delighted to see that the most able and distinguished Senator from South Carolina and President pro tempore of the Senate has joined us. That must mean, Senator, that the Senate is temporarily under control.

If you have either an opening statement or any questions, we will be glad to yield for them at this point.

Senator THURMOND. Thank you very much, Mr. Chairman.

I wanted to ask this question. I notice in this bill, S. 827, of Senator Hawkins and others, that they are recommending in the event of death, compensation not less than $300,000 or more than $700,000; and for pain and suffering and emotional stress, not to exceed $100,000.

Now, I understand that the companies claim that they will go out of business unless something is done to limit these amounts. I am wondering if you have any comment on that?

Mr. COLANTONI. Senator, I think that if we can demonstrate in a civil suit that the vaccine manufacturers are negligent, or that they have, in fact, made a defective vaccine, and had the technology to make a safe product but has chosen not to do so, then, I think, they should be subject to whatever damages are awarded in a civil suit. That essentially is the price of business, the risks that they take by engaging in that type of conduct. And I personally have a lot of faith in our system as it exists. Where a manufacturer drops out and there is a demand for a particular product, another manufacturer will fill the course.

And the question was raised earlier about all of the vaccine manufacturers in this country going out of business. I cannot see why we cannot go to Japan for a source of vaccine. They have, as I understand it, at least six companies producing an acellular vaccine which is less reactive than the current wholecell product. And I think that any one of those companies might very well be willing to come over here and produce a vaccine for our American children.

Senator THURMOND. Well, I am just concerned—we do not want companies to go out of business—I am sure you agree with that.

Mr. COLANTONI. Yes.

Senator THURMOND. And I understand they say they will go out of business unless there is some limit put on it. I was a damage suit lawyer myself before I came to the Senate. On the other hand, I am trying to look at it from the standpoint of the public and what is best. And if we need this vaccine and we cannot get it, then a lot of children will probably die because of it. I understand the vaccine has only caused a few deaths, a very small percentage, but yet the verdicts that have been obtained, I understand, are excessive, and it places the companies in a position where they will not continue unless some limit is put on it.

Are these reasonable limits, $300,000 to $700,000 for a death?

Mr. COLANTONI. Under the bill, $300,000 to $700,000 is, quite frankly, very reasonable limits. I think that the value of the life of a child, to put it bluntly, in civil suits throughout the country varies. But I do not think it is unreasonable that it falls within that type of range. So when we compare the——

Senator THURMOND. What I am asking you is, is this a reasonable amount for a child who may die, $300,000 to $700,000, to go to the parents or the next of kin?

Mr. COLANTONI. Well, I have trouble with that question because is any amount really a reasonable amount when you are talking about the death of a child? But certainly, this is a reasonable response to a very difficult question, yes.

Senator THURMOND. And pain and suffering, up to $100,000; is that reasonable?

Mr. COLANTONI. I think that is totally inadequate, Senator, the $100,000 limitation.

Senator THURMOND. I see. I just wanted to get your opinion about it.

Does anyone else have a comment on that?

Mr. CORRIN. I would like to address your first question about the companies going out of business. I know in the polio case that I am involved in, there was evidence that several manufacturers were invited to manufacture the live polio virus back in 1961, the live vaccine, and declined because there was not any evidence that it was safe. And those manufacturers at that time were manufacturing the killed vaccine and so were some others. And if it turns out that the live vaccine is a dangerous vaccine and that the killed vaccine is more safe, and that the company that—I do not think that Lederle Laboratories is going to go out of business—but if the litigation over the people that they give polio, which are not all children, like the whooping cough always gets, if they are going to stop manufacturing the live vaccine, that there are at least a lot of companies around that can manufacture a safe vaccine that will protect the public from the spread of polio.

Senator STAFFORD. If the Senator would yield just a minute, I think, Senator, that you have raised a basic issue we have been discussing here, and that is something of a unique situation, because if the committee is not misinformed, only Lederle is left manufacturing the whooping cough vaccine at the present time; other manufacturers have stopped. And I think the earlier panel of witnesses indicated that the price of the polio and diptheria and whooping cough vaccine, at least in Vermont, the annual cost went from something in the low thousands, $3,000 or $4,000, if I recall correctly, to something like $80,000 last year because of single-source procurement, I assume. So whatever the reaction of attorneys to the tort system, we do have a rather unique problem facing the country in terms of the fact that we have one manufacturer left. Even if there are overseas manufacturers who might come in here, they certainly have not arrived in time to alleviate the cost of the vaccines up until present. That is the problem that I think is facing the country.

Dr. Shapo.

Dr. SHAPO. Senator, I would just like to refer to something I said in my prepared remarks, which is that I wonder what the peculiarity is in the business of insuring vaccine injuries that has produced this situation: You have a product that it is generally agreed is a necessary and vital product. More broadly you have market prices that reflect the costs imposed by the tort liability system, which applies across the board to all productmakers, cab drivers, physicians,

and anyone who engages in risky activity. What is it that is peculiar about this particular product that produces a situation in which the market prices, embodying liability costs, have brought us to a pass where there is one manufacturer? I do not know the answer to that question, but it would seem to me that before you begin to revise the common law for a particular product that it would be very important to have the answer to that question.

Senator THURMOND. Thank you very much. I have another appointment. Thank you very much, Mr. Chairman.

Senator STAFFORD. Thank you, Senator Thurmond, very much indeed.

Mr. Colantoni, you reminded me in part of your statement about if the potential wrongdoer can calculate with certainty punitive damages, he may decide just to pay them as a part of the cost of doing business. I must recall—all committee chairmen are allowed to recall a little bit—that when I was State's attorney of my home county a good many years ago, the logging industry found that they could violate our over-the-highway weight regulations by overloading their trucks enough money so that they made quite a little bit more on hauling the logs than we were able to fine them under the then existing laws in Vermont. In a way, you are saying that that could happen here in the vaccine industry.

Mr. COLANTONI. Yes, Senator. I think that the beauty of the present system is that damages are uncertain, and the uncertainty forces people into socially acceptable conduct. If they are able to calculate the damages, they can put it into an equation and write it off as a cost of doing business, and that is something that we must avoid.

Senator STAFFORD. Since all three of you are lawyers, I am also reminded that at a somewhat later date, I was attorney general of Vermont, and in that guise issued a number of opinions in writing. Sometime after that, I became the Governor of the State and had one pet project that I wished to get through the legislature, only to be informed by a successor attorney general that in his opinion it was unconstitutional. So I demanded that he repair to my office immediately and indicate why he so thought. He arrived and said he had an opinion from a New Hampshire supreme court and another opinion by an attorney general of Vermont. When I asked him, "What damn fool wrote the Vermont attorney general's opinion?" he said, looking me in the eye, "It was some damn fool whose initials are 'R.T.S.' "

Since those are my initials, we were forced to withdraw our request to the legislature. I hope that never happens to any of you.

Each of you has some experience with current practices and procedures relating to the manufacture, distribution and administration of vaccines. Do you believe that children are now being immunized in the United States with the safest possible vaccines administered in the safest possible way? I assume your answer might be "No" to that.

Second, do you believe that establishing a system which eliminates liability for the current vaccines administered in the current way will make for a system which is more or less safe for tomorrow's children?

Mr. Colantoni.

Mr. COLANTONI. Senator, I think the answer is obvious. The current wholecell vaccine in the United States is the most reactive, the least pure vaccine available. And I think we have developed evidence through the litigation process that as early as the early 1960's, manufacturers in this country had the capability to make a less reactive vaccine and simply chose, for whatever reason, not to do so. And they have known that the vaccine that we have on the market now is toxic and causes serious adverse neurological reactions.

So we do not have the safest vaccine on the market. And again, I would submit that the evidence is very clear on that point.

Senator STAFFORD. Does anybody else wish to respond to that?

Mr. CORRIN. I would say that the immunization or protection of the current manufacturers and the current vaccines would have exactly the opposite effect. It would give them no incentive to make any vaccines that were safer. And the system that exists now is the one engine that we have to try and force progress and more safety.

Senator STAFFORD. Dr. Shapo.

Dr. SHAPO. Well, I think it would now be superfluous.

Senator STAFFORD. All right.

Mr. Colantoni, one of the arguments frequently advanced against the current tort system is that it encourages so-called frivolous lawsuits. It is my understanding that your firm works on a contingency basis. If this is not privileged information, would you be willing to indicate what the contingency basis is that you operate on?

Mr. COLANTONI. The contingent fee contracts that our clients sign are usually a 33⅓ percent to 40 percent basis, depending on exactly how far the suit goes.

As a practical matter, Senator, I think the percentage of fees that we take out of a settlement is somewhere between 25 to 30 percent. In several cases, in order to effect a settlement, the percentage of the total amount that we take as a fee is less than that—sometimes, around 20 percent.

So, while contractually, we are entitled to as much as 40 percent, that often is not the case.

Senator STAFFORD. I think you indicated in your previous testimony that you have an average cost of a case which you prepare for trial of about $100,000?

Mr. COLANTONI. That is correct.

Senator STAFFORD. Does that involve cost of trial, as well?

Mr. COLANTONI. Yes, Senator, it does.

Senator STAFFORD. That is the total cost of presenting the case.

Mr. COLANTONI. Total cost.

Senator STAFFORD. What proportion of prospective clients that my come to you do you actually take on? That is, how many do you screen out; what proportion don't you accept?

Mr. COLANTONI. Essentially, we will look at the file of just about anyone who comes into the office. In the DPT area, we probably decline representation in about half of the cases that come through the door, currently—perhaps a little more.

Senator STAFFORD. Are you extensively in this kind of business too, Mr. Corrin?

Mr. CORRIN. Yes, Senator.

Senator STAFFORD. Would you agree generally with what Mr. Colantoni has said?

Mr. CORRIN. Well, I think that is right, when you are working on a contingency fee basis, and when you are usually putting up most of the expenses in advance yourself, because your client does not have the money to pay you an hourly fee, or to pay $100,000 to pursue a lawsuit, the last thing you want is a frivolous suit.

Senator STAFFORD. I think Mr. Colantoni said his firm represents about 175 prospective clients who are involved in vaccine litigation. How many do you represent?

Mr. CORRIN. Well, I am just involved in the one polio case, because I was brought in mainly to handle the appeal. But I do do a fair amount of medical negligence and product liability work at the trial level.

Senator STAFFORD. All right.

Mr. Colantoni, I understand that you may have lost one piece of vaccine litigation because the jury did not believe that the Government would sanction the production of a vaccine that was not safe.

Am I correct in that? Could you comment briefly on that, if I am correct?

Mr. COLANTONI. Yes, Senator. The case was *Malek* v. *Lederle Laboratories,* and it was tried in Chicago in December 1982. It was about a 2½-week trial. The jury deliberated for about 10 hours over 2 days, as I recall. And they returned a verdict for Lederle Laboratories.

In talking to them, one of the main things that they pointed out was that they did not believe that the Government would sanction a vaccine that caused so much injury. They felt that if the vaccine was as bad as our experts claimed that it was, and that if it caused so much injury, as we claimed it did, that it would not be on the market. And we found it very difficult to overcome at that point.

Of course, in the ensuing 3 years, we have learned a whole lot more about the Federal regulatory process and about the DPT vaccine in particular, and now I am glad to say we have been awarded a new trial in that particular case and hope to try the case sometime in 1986.

Senator STAFFORD. One last question. Dr. Shapo, is there any precedent for requiring a victim to give up his right to sue as a condition of assistance?

Dr. SHAPO. Well, I am not sure of any, Senator. Obviously, there are some compensation systems that have totally supplanted the tort system, such as workers compensation. There does seem to be some evidence that workers compensation is beginning to generate more litigation and perhaps moving back toward the tort system a little bit.

I wonder, though, if I could refer to a point that you were just discussing concerning Government regulations. As perhaps is appropriate in my role, it is a fairly theoretical point, but it arises from the study that I recently did do on the tort system taken as a whole. A long chapter deals with the systems of safety regulations that border the tort system, and the insight of that study such as it is, is that the tort system provides a kind of bulwark against swings of the political pendulum; that if you look at the history of safety agencies over the years, that you will find that there are

several of them that have sort of expanded and then contracted their roles. And it seems to me that tort law provides a kind of gyroscopic mechanism that gives you at least a certain evenness and a certain stability as the political seas shift around.

Senator STAFFORD. Thank you very much, gentlemen. You have been very helpful, and for the committee, I want to express our appreciation.

I know how much trouble you have gone to be here, and I want you to know that I personally appreciate it very much.

Thank you all.

Senator STAFFORD. The committee stands adjourned.

[Whereupon, at 11:40 a.m., the subcommittee was adjourned.]

[Additional material submittted for the record follows:]

STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Committee on Labor and Human Resources
United States Senate

RE: Vaccine-Injury Compensation

December 4, 1985

This is the third time in the last 18 months that the American Medical Association has submitted it views on the vaccine injury issue to this Committee. Throughout the Congressional policy debate on vaccine injury compensation and liability issues, the AMA has based its policy on the achievement of four goals:

1. The assurance of the continued development and availability of pediatric vaccines.
2. The assurance of continued participation of physicians and other qualified persons in the administration of pediatric vaccines.
3. The assurance of appropriate vaccination of all children.
4. The promotion of the identification and equitable compensation of persons injured by severe reactions to pediatric vaccines.

It has been our view that in order to better achieve these broad policy goals, a federal legislative program should be established for appropriate compensation of persons seriously injured as a result of state or federally mandated pediatric immunization.

There is widespread support for some form of government-directed compensation system to supplement or replace the current civil tort remedy as the principal means of compensating those injured by mandated pediatric vaccines.

There still remains a difference in view as to the scope and implementing details of such a compensation program.

The AMA's view has been, and continues to be, that the most desirable vaccine compensation program would be a program established as the sole recourse for those seriously injured by mandated vaccines. We believe that such an approach would provide stability in the tort litigation environment necessary to assure a stable supply of vaccines at reasonable prices. In addition, it would provide prompt, no-fault compensation for all serious injuries arising from mandated childhood vaccines. We developed draft legislation to establish such a federal program.

At the hearing before this Committee last July, we related our continued opposition to the compeneation program proposed in the original version of S. 827. In spite of a number of improvements from last year's version of this legislation, the AMA cannot support the establishment of the federal compensation program as an option to the traditional tort remedy, rather than being the sole source of compensation for vaccine-related injuries. Given the important goals of promoting the vaccination of children and assuring the ready availability of vaccine to meet that objective, legislation should be fashioned to help achieve those goals. Permitting claimants to continue to bring tort actions against manufacturers and providers will not, in our view, achieve desired goals since sufficient protection is not provided from the increasingly high

expense of litigation that is driving manufacturer costs up--costs that have been asserted as forcing companies out of vaccine production.

Beneficial legislation should strike a fair balance between the desirable goal of compensating victims of serious vaccine injuries and the need for vaccine producing companies to operate in an environment with some measure of protection from the extremely high legal costs in this complicated area of law. While S. 827 seeks to meet the desirable goal of affording relief to individuals suffering injuries who otherwise would have no remedy for compensation, by preserving the private tort remedy as an additional option the bill does not overcome the principal factors causing current problems and therefore would not promote the desirable goal of providing for continued availability of vaccines at reasonable costs and maximum immunization of our population.

At last July's hearing, we discussed our willingness to embrace certain modifications to pending compensation legislation, notwithstanding our fundamental preference for the exclusive compensation remedy approach. Although we remain opposed to an independent dual remedy approach such as found in the original S. 827, we believe that a modified no-fault system that would remove vaccine injury cases from the existing tort system may be an effective way to assure a continued supply of vaccines, their timely administration and promotion of public participation. A proposed compensation system can embrace a modified no-fault compensation program by using a system similar to that proposed in the House bill, H.R. 1780.

The legislation we have in mind should provide a no-fault entry into the claims review process. Claims for damages in the compensation

program contemplated in H.R. 1780, however, should be assessed only against manufacturers. Manufacturers should be allowed to recover all expenses and compensation payments from any party who was at fault. If more than one party was at fault, damages would be apportioned to reflect comparative negligence.

The "Stafford Amendment". As originally introduced, S. 827 provided that a vaccine-injured person could elect to seek compensation under the federal program as an alternative to filing a tort action. If a person did choose to file for an award under the compensation program, he or she would be barred from filing a tort action; and if a lawsuit was filed (after enactment) an award under the compensation system would be precluded.

The Stafford Amendment would alter this provision. In essence, it would maintain the compensation program as an option, but would provide that if a compensation award was granted, any award amounts received by the claimant would have to be repaid to the program from any proceeds or sums awarded in judgment or settlement of a tort claim.

This amendment appears to us to be a step backward from the original bill. At least in the original S. 827, a claimant had to make an initial irrevocable choice between the compensation program and the tort system. Under the Stafford Amendment, the claimants can evidently pursue the government compensation program at their option, receive an award or not, and then try their luck in the tort system. Given the huge amount of many court judgments these days, many claimants would likely be undeterred by the prospect of having to return a small part of a large court award to the program. Indeed, since the compensation program's

determinations, qualifications, aids, and studies may all be admitted into evidence in any subsequent tort suit, a favorable award by that program may be an open invitation to the claimant to try his or her luck in the tort system. In sum, we view the Stafford Amendment as compounding all of the defects of the original S. 827.

"Discussion Draft of October 25". A step in the right direction, in our view, was language contained in an earlier version of the Committee's October 25 Discussion Draft which stated that any person who sustained a vaccine-related injury "must apply for compensation under the program before filing an action in a state or federal court for damages." This approach also provides that the "acceptance of an award" under the program would trigger the permanent bar on tort filings (as opposed to the mere filing for government compensation.) (This language has subsequently been dropped and the current draft contains the original S. 827 language).

While we prefer an exclusive remedy, we are willing to embrace the notion that persons be required to initially pursue a compensation program. This procedure is the basis of H.R. 1780, which would establish a modified no-fault system for vaccine-compensation that requires all claims for damages allegedly caused by a vaccine to be first submitted to a three-person hearing panel.

In that bill, all potential claimants must file their claim in the "no-fault" compensation program, naming parties involved. Respondents elect whether to participate, but failure to participate exposes them to civil tort action and to unlimited damages in such an action. The panel would determine causation and if the panel determined that the injury was

"vaccine-related" it could make an award for actual damages of up to $1 million including pain and suffering. An award for pain and suffering could not exceed $100,000. Liability actions could still be filed in cases where the injured party does not accept the award offered (though maximum damages would be limited by the caps in cases where a respondent did participate in the compensation process).

We believe that any approach that requires claimants to pursue a mandatory initial compensation route is preferable to the election permitted under S. 827 as originally introduced and also preferable to the Stafford Amendment to S. 827. We believe that the House bill approach lays out a plausible basis for further legislative development.

Conclusion

The AMA remains committed to achieving a solution to the on-going crisis in vaccine liability. We urge this Committee to continue to give careful consideration to all of the implications of different compensation system designs, including the impact on the liability and litigation environment and vaccine supply.

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